

IN THE UNITED STATES DISTRICT COURT  
FOR THE WESTERN DISTRICT OF TEXAS  
WACO DIVISION

ALIGN TECHNOLOGY, INC.,

Plaintiff and  
Counterclaim-  
Defendant,

v.

3SHAPE TRIOS A/S and 3SHAPE A/S,

Defendants and  
Counterclaim-Plaintiffs.

Civil Action No. 6:20-cv-00979-ADA

**DEFENDANTS 3SHAPE TRIOS A/S AND 3SHAPE A/S’S  
SECOND AMENDED CONTINGENT ANSWER, AFFIRMATIVE DEFENSES,  
AND COUNTERCLAIMS**

On December 2, 2020, Defendants 3Shape A/S and 3Shape Trios A/S (“3Shape” or “Defendants”) filed their Motion to Dismiss Pursuant to Federal Rule of Civil Procedure 12(b)(7) or, in the alternative, Transfer to the United States District Court for the District of Delaware (Dkt. No. 21 (“Motion”)). Thus, subject to and only in the event the Court denies Defendants’ Motion,<sup>1</sup> Defendants hereby contingently answer Plaintiff Align Technology, Inc.’s (“Align”) First Amended Complaint and present their current affirmative defenses. In addition, 3Shape (in this context, “Counterclaim-Plaintiffs”) hereby present, likewise subject to and only in the event the Court denies their Motion, amended contingent counterclaims. Any admissions herein are for purposes of this matter only. 3Shape reserves the right to modify its Answer and raise additional defenses and/or counterclaims that may become apparent as a result of additional information discovered subsequent to filing this Contingent Answer.

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<sup>1</sup> This Court indicated it will deny 3Shape’s Motion to Transfer. (Jan. 29, 2021 Hr’g Tr. at 6:14-19.) 3Shape’s Motion to Dismiss under Rule 12(b)(7) is currently pending. (See Mar. 23, 2021 Hr’g Tr. at 20:4-18.)

### **THE PARTIES**

1. Defendants deny the allegations of paragraph 1, except Defendants admit on information and belief that Align is a Delaware corporation with its principal place of business in San Jose, California.
2. Defendants admit that 3Shape A/S is a Danish corporation with a principal place of business at Holmens Kanal 7, 1060 Copenhagen K, Denmark.
3. Defendants admit that 3Shape Trios A/S is a Danish corporation with a principal place of business at Holmens Kanal 7, 1060 Copenhagen K, Denmark.
4. This paragraph contains legal conclusions to which no response is required. To the extent there are any remaining allegations in paragraph 4 not addressed by the foregoing, Defendants deny them.

### **JURISDICTION AND VENUE**

5. This paragraph contains legal conclusions to which no response is required. To the extent any response is required, Defendants admit that Plaintiff purports to bring this action under the patent laws of the United States, pursuant to Title 35 of the United States Code. To the extent there are any remaining allegations in paragraph 5 not addressed by the foregoing, Defendants deny them.
6. This paragraph contains legal conclusions to which no response is required. To the extent any response is required, Defendants admit that this Court generally has subject matter jurisdiction over actions arising under 28 U.S.C. §§ 1331 and 1338, but deny that Plaintiff is entitled to any relief thereunder. To the extent there are any remaining allegations in paragraph 6 not addressed by the foregoing, Defendants deny them.
7. This paragraph contains legal conclusions to which no response is required. To the extent there are any remaining allegations in paragraph 7 not addressed by the foregoing, Defendants deny them.

8. Defendants deny all allegations contained within paragraph 8.

9. Defendants deny all allegations contained within paragraph 9.

10. Defendants deny all allegations contained within paragraph 10.

11. This paragraph contains legal conclusions to which no response is required. To the extent there are any remaining allegations in paragraph 11 not addressed by the foregoing, Defendants deny them.

12. This paragraph contains legal conclusions to which no response is required. To the extent there are any remaining allegations in paragraph 12 not addressed by the foregoing, Defendants deny them, including for the reasons in Defendants’ Motion.

### **BACKGROUND**

13. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 13, and therefore deny them.

14. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 14, and therefore deny them.

15. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 15, and therefore deny them.

16. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 16, and therefore deny them.

17. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 17, and therefore deny them.

18. Defendants deny all allegations contained within paragraph 18.

19. Defendants deny the allegations of paragraph 19, except Defendants admit that the Trios and iTero scanners compete against each other in the Market for Scanners for Orthodontic Treatment.

20. Defendants deny all allegations contained within paragraph 20.

### THE ASSERTED COLOR SCANNING PATENTS

21. This paragraph contains legal conclusions to which no response is required. To the extent there are any remaining allegations in paragraph 21 not addressed by the foregoing, Defendants deny them.

22. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 22, and therefore deny them.

23. This paragraph contains legal conclusions to which no response is required. To the extent there are any remaining allegations in paragraph 23 not addressed by the foregoing, Defendants deny them.

24. Defendants deny the allegations contained within paragraph 24, except Defendants admit that U.S. Patent No. 9,101,433 (the “’433” patent) was previously the subject of an *inter partes* review filed by 3Shape A/S in the Patent and Trademark Office.

25. Defendants deny the allegations of paragraph 25, except Defendants admit that the U.S. Patent Nos. 8,363,228 (the “’228 patent”), 8,451,456 (the “’456 patent”), 8,675,207 (the “’207 patent”), and the ’433 patent were previously the subject of an International Trade Commission (“ITC”) investigation. Paragraph 25 omits that the ITC found that 3Shape does not infringe the ’433 patent. Paragraph 25 also omits that the ITC found the asserted claims of each of the ’228, ’456, and ’207 patents invalid, and Align did not challenge those findings on appeal. *Certain Color Intraoral Scanners and Related Hardware and Software*, Inv. No. 337-TA-1091, Comm’n Op. (Dec. 19, 2020) (public version attached hereto as Exhibit 1.)

26. Defendants admit that the ’433 patent states that it issued on August 11, 2015. Defendants admit that the ’519 patent states that it issued on July 28, 2020. Defendants admit that the ’151 and ’152 patents state that they issued on August 18, 2020. To the extent there are any remaining allegations in paragraph 26 not addressed by the foregoing, Defendants deny them.

27. Defendants deny all allegations contained within paragraph 27.

**THE ASSERTED SELECTIVE RESCANNING PATENTS**

28. This paragraph contains legal conclusions to which no response is required. To the extent there are any remaining allegations in paragraph 28 not addressed by the foregoing, Defendants deny them.

29. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 29 and therefore deny them.

30. This paragraph contains legal conclusions to which no response is required. To the extent there are any remaining allegations in paragraph 30 not addressed by the foregoing, Defendants deny them.

31. Defendants deny the allegations of paragraph 31, except Defendants admit that the U.S. Patent No. 9,299,192 (the “’192 patent”) was previously the subject of an International Trade Commission (“ITC”) investigation. Paragraph 31 omits that the ITC found the asserted claims of the ’192 patent invalid. 1144 Investigation, Comm’n Op. (Nov. 17, 2020) (public version attached hereto as Exhibit 2). Paragraph 31 also omits that the Patent and Trial and Appeal Board (“PTAB”) similarly found all challenged claims of the ’192 patent invalid during an *inter partes* review (“IPR”) initiated by 3Shape. *3Shape A/S and 3Shape Inc. v. Align Tech., Inc.*, IPR2019-00134, Final Written Decision (July 20, 2020) (attached hereto as Exhibit 3).

32. Defendants admit that the ’609 and ’936 patents state they were issued on March 16, 2021 and October 6, 2020, respectively. To the extent there are any remaining allegations in paragraph 32 not addressed by the foregoing, Defendants deny them.

**THE ASSERTED HOLE-CLOSING TECHNOLOGY PATENT**

33. This paragraph contains legal conclusions to which no response is required. To the extent there are any remaining allegations in paragraph 33 not addressed by the foregoing, Defendants deny them.

34. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 34 and therefore deny them.

35. This paragraph contains legal conclusions to which no response is required. To the extent there are any remaining allegations in paragraph 35 not addressed by the foregoing, Defendants deny them.

36. Defendants admit that the ’527 patent states it was issued on July 14, 2020. To the extent there are any remaining allegations in paragraph 36 not addressed by the foregoing, Defendants deny them.

**COUNT ONE – INFRINGEMENT OF THE ’433 PATENT**

37. Defendants restate and reincorporate their response to paragraphs 1-36 as if fully set forth herein.

38. Defendants admit that the ’433 patent states it was issued on August 11, 2015. Defendants admit the ’433 patent is entitled “Method and Apparatus for Colour Imaging a Three-Dimensional Structure.” To the extent there are any remaining allegations in paragraph 38 not addressed by the foregoing, Defendants deny them.

39. Defendants deny all allegations contained within paragraph 39.

40. Defendants deny all allegations contained within paragraph 40.

41. Defendants deny all allegations contained within paragraph 41.

42. Defendants deny all allegations contained within paragraph 42.

43. Defendants deny all allegations contained within paragraph 43.

- 44. Defendants deny all allegations contained within paragraph 44.
- 45. Defendants deny all allegations contained within paragraph 45.
- 46. Defendants deny all allegations contained within paragraph 46.
- 47. Defendants deny all allegations contained within paragraph 47.
- 48. Defendants deny all allegations contained within paragraph 48.
- 49. Defendants deny all allegations contained within paragraph 49.

**COUNT TWO – INFRINGEMENT OF THE ’519 PATENT**

50. Defendants restate and reincorporate their response to paragraphs 1-49 as if fully set forth herein.

51. Defendants admit that the ’519 patent states it was issued on July 28, 2020. Defendants admit the ’519 patent is entitled “Method and Apparatus for Colour Imaging a Three-Dimensional Structure.” To the extent there are any remaining allegations in paragraph 51 not addressed by the foregoing, Defendants deny them.

- 52. Defendants deny all allegations contained within paragraph 52.
- 53. Defendants deny all allegations contained within paragraph 53.
- 54. Defendants deny all allegations contained within paragraph 54.
- 55. Defendants deny all allegations contained within paragraph 55.
- 56. Defendants deny all allegations contained within paragraph 56.
- 57. Defendants deny all allegations contained within paragraph 57.
- 58. Defendants deny all allegations contained within paragraph 58.
- 59. Defendants deny all allegations contained within paragraph 59.
- 60. Defendants deny all allegations contained within paragraph 60.
- 61. Defendants deny all allegations contained within paragraph 61.
- 62. Defendants deny all allegations contained within paragraph 62.

63. Defendants deny all allegations contained within paragraph 63.

**COUNT THREE – INFRINGEMENT OF THE ’151 PATENT**

64. Defendants restate and reincorporate their response to paragraphs 1-63 as if fully set forth herein.

65. Defendants admit that the ’151 patent states it was issued on August 18, 2020. Defendants admit the ’151 patent is entitled “Method and Apparatus for Colour Imaging a Three-Dimensional Structure.” To the extent there are any remaining allegations in paragraph 65 not addressed by the foregoing, Defendants deny them.

66. Defendants deny all allegations contained within paragraph 66.

67. Defendants deny all allegations contained within paragraph 67.

68. Defendants deny all allegations contained within paragraph 68.

69. Defendants deny all allegations contained within paragraph 69.

70. Defendants deny all allegations contained within paragraph 70.

71. Defendants deny all allegations contained within paragraph 71.

72. Defendants deny all allegations contained within paragraph 72.

73. Defendants deny all allegations contained within paragraph 73.

74. Defendants deny all allegations contained within paragraph 74.

75. Defendants deny all allegations contained within paragraph 75.

76. Defendants deny all allegations contained within paragraph 76.

77. Defendants deny all allegations contained within paragraph 77.

**COUNT FOUR – INFRINGEMENT OF THE ’152 PATENT**

78. Defendants restate and reincorporate their response to paragraphs 1-77 as if fully set forth herein.



79. Defendants admit that the ’152 patent states it was issued on August 18, 2020. Defendants admit the ’152 patent is entitled “Method and Apparatus for Structure Imaging a Three-Dimensional Structure.” To the extent there are any remaining allegations in paragraph 79 not addressed by the foregoing, Defendants deny them.

80. Defendants deny all allegations contained within paragraph 80.

81. Defendants deny all allegations contained within paragraph 81.

82. Defendants deny all allegations contained within paragraph 82.

83. Defendants deny all allegations contained within paragraph 83.

84. Defendants deny all allegations contained within paragraph 84.

85. Defendants deny all allegations contained within paragraph 85.

86. Defendants deny all allegations contained within paragraph 86.

87. Defendants deny all allegations contained within paragraph 87.

88. Defendants deny all allegations contained within paragraph 88.

89. Defendants deny all allegations contained within paragraph 89.

90. Defendants deny all allegations contained within paragraph 90.

91. Defendants deny all allegations contained within paragraph 91.

#### **COUNT FIVE – INFRINGEMENT OF THE ’609 PATENT**

92. Defendants restate and reincorporate their response to paragraphs 1-91 as if fully set forth herein.

93. Defendants admit that the ’609 patent states it was issued on March 16, 2021. Defendants admit the ’609 patent is entitled “Systems and Methods for Accounting for Changes in Surface Topology When Scanning a Patient’s Teeth.” To the extent there are any remaining allegations in paragraph 93 not addressed by the foregoing, Defendants deny them.

94. Defendants deny all allegations contained within paragraph 94.

- 95. Defendants deny all allegations contained within paragraph 95.
- 96. Defendants deny all allegations contained within paragraph 96.
- 97. Defendants deny all allegations contained within paragraph 97.
- 98. Defendants deny all allegations contained within paragraph 98.
- 99. Defendants deny all allegations contained within paragraph 99.
- 100. Defendants deny all allegations contained within paragraph 100.
- 101. Defendants deny all allegations contained within paragraph 101.
- 102. Defendants deny all allegations contained within paragraph 102.
- 103. Defendants deny all allegations contained within paragraph 103.
- 104. Defendants deny all allegations contained within paragraph 104.

**COUNT SIX – INFRINGEMENT OF THE '936 PATENT**

105. Defendants restate and reincorporate their response to paragraphs 1-104 as if fully set forth herein.

106. Defendants admit that the '936 patent states it was issued on October 6, 2020. Defendants admit the '936 patent is entitled “Methods and Systems for Creating and Interacting With Three Dimensional Virtual Models.” To the extent there are any remaining allegations in paragraph 106 not addressed by the foregoing, Defendants deny them.

- 107. Defendants deny all allegations contained within paragraph 107.
- 108. Defendants deny all allegations contained within paragraph 108.
- 109. Defendants deny all allegations contained within paragraph 109.
- 110. Defendants deny all allegations contained within paragraph 110.
- 111. Defendants deny all allegations contained within paragraph 111.
- 112. Defendants deny all allegations contained within paragraph 112.
- 113. Defendants deny all allegations contained within paragraph 113.

- 114. Defendants deny all allegations contained within paragraph 114.
- 115. Defendants deny all allegations contained within paragraph 115.
- 116. Defendants deny all allegations contained within paragraph 116.
- 117. Defendants deny all allegations contained within paragraph 117.

**COUNT SEVEN – INFRINGEMENT OF THE '527 PATENT**

118. Defendants restate and reincorporate their response to paragraphs 1-117 as if fully set forth herein.

119. Defendants admit that the '527 patent states it was issued on July 14, 2020. Defendants admit the '527 patent is entitled “Method of Manipulating a Dental Virtual Model, Method for Creating Physical Entities Based on a Dental Virtual Model Thus Manipulated, and Dental Models Thus Created.” To the extent there are any remaining allegations in paragraph 119 not addressed by the foregoing, Defendants deny them.

- 120. Defendants deny all allegations contained within paragraph 120.
- 121. Defendants deny all allegations contained within paragraph 121.
- 122. Defendants deny all allegations contained within paragraph 122.
- 123. Defendants deny all allegations contained within paragraph 123.
- 124. Defendants deny all allegations contained within paragraph 124.
- 125. Defendants deny all allegations contained within paragraph 125.
- 126. Defendants deny all allegations contained within paragraph 126.
- 127. Defendants deny all allegations contained within paragraph 127.
- 128. Defendants deny all allegations contained within paragraph 128.
- 129. Defendants deny all allegations contained within paragraph 129.

### **PRAYER FOR RELIEF**

Defendants deny that Plaintiff is entitled to any of the relief requested by the Amended Complaint or any other remedy or relief whatsoever.

### **CONTINGENT AFFIRMATIVE DEFENSES**

Without any admission as to the burden of proof, burden of persuasion, or the truth of any of the allegations in Plaintiff’s Complaint, Defendants state the following contingent affirmative defenses. Defendants reserve the right to assert additional defenses, as warranted by the facts learned through investigation and discovery.

#### **First Affirmative Defense** **(Invalidity and/or Unenforceability of U.S. Patent No. 9,101,433)**

One or more claims of the ’433 patent are invalid and/or unenforceable for failure to comply with one or more of the requirements for patentability set forth in Title 35 of the U.S. Code, including §§ 101, 102, 103, 112, and 116 and/or invalid under any other ground provided by 35 U.S.C. § 282, and/or based on other judicially-created bases for invalidity or unenforceability.

#### **Second Affirmative Defense** **(Non-Infringement of U.S. Patent No. 9,101,433)**

Plaintiff has failed to aver any facts that support its allegations of infringement by the accused products. The accused products do not infringe any valid and enforceable claim of the ’433 patent, either literally or under the doctrine of equivalents.

#### **Third Affirmative Defense** **(Invalidity and/or Unenforceability of U.S. Patent No. 10,728,519)**

One or more claims of the ’519 patent are invalid and/or unenforceable for failure to comply with one or more of the requirements for patentability set forth in Title 35 of the U.S. Code, including §§ 101, 102, 103, 112, and 116 and/or invalid under any other ground provided by 35 U.S.C. § 282, and/or based on other judicially-created bases for invalidity or unenforceability.

**Fourth Affirmative Defense**  
**(Non-Infringement of U.S. Patent No. 10,728,519)**

Plaintiff has failed to aver any facts that support its allegations of infringement by the accused products. The accused products do not infringe any valid and enforceable claim of the '519 patent, either literally or under the doctrine of equivalents.

**Fifth Affirmative Defense**  
**(Invalidity and/or Unenforceability of U.S. Patent No. 10,750,151)**

One or more claims of the '151 patent are invalid and/or unenforceable for failure to comply with one or more of the requirements for patentability set forth in Title 35 of the U.S. Code, including §§ 101, 102, 103, 112, and 116 and/or invalid under any other ground provided by 35 U.S.C. § 282, and/or based on other judicially-created bases for invalidity or unenforceability.

**Six Affirmative Defense**  
**(Non-Infringement of U.S. Patent No. 10,750,151)**

Plaintiff has failed to aver any facts that support its allegations of infringement by the accused products. The accused products do not infringe any valid and enforceable claim of the '151 patent, either literally or under the doctrine of equivalents.

**Seventh Affirmative Defense**  
**(Invalidity and/or Unenforceability of U.S. Patent No. 10,750,152)**

One or more claims of the '152 patent are invalid and/or unenforceable for failure to comply with one or more of the requirements for patentability set forth in Title 35 of the U.S. Code, including §§ 101, 102, 103, 112, and 116 and/or invalid under any other ground provided by 35 U.S.C. § 282, and/or based on other judicially-created bases for invalidity or unenforceability.

**Eighth Affirmative Defense**  
**(Non-Infringement of U.S. Patent No. 10,750,152)**

Plaintiff has failed to aver any facts that support its allegations of infringement by the accused products. The accused products do not infringe any valid and enforceable claim of the '152 patent, either literally or under the doctrine of equivalents.

**Ninth Affirmative Defense**  
**(Invalidity and/or Unenforceability of U.S. Patent No. 10,709,527)**

One or more claims of the '527 patent are invalid and/or unenforceable for failure to comply with one or more of the requirements for patentability set forth in Title 35 of the U.S. Code, including §§ 101, 102, 103, 112, and 116 and/or invalid under any other ground provided by 35 U.S.C. § 282, and/or based on other judicially-created bases for invalidity or unenforceability.

**Tenth Affirmative Defense**  
**(Non-Infringement of U.S. Patent No. 10,709,527)**

Plaintiff has failed to aver any facts that support its allegations of infringement by the accused products. The accused products do not infringe any valid and enforceable claim of the '527 patent, either literally or under the doctrine of equivalents.

**Eleventh Affirmative Defense**  
**(Invalidity and/or Unenforceability of U.S. Patent No. 10,945,609)**

One or more claims of the '609 patent are invalid and/or unenforceable for failure to comply with one or more of the requirements for patentability set forth in Title 35 of the U.S. Code, including §§ 101, 102, 103, 112, and 116 and/or invalid under any other ground provided by 35 U.S.C. § 282, and/or based on other judicially-created bases for invalidity or unenforceability.

**Twelfth Affirmative Defense**  
**(Non-Infringement of U.S. Patent No. 10,945,609)**

Plaintiff has failed to aver any facts that support its allegations of infringement by the accused products. The accused products do not infringe any valid and enforceable claim of the '609 patent, either literally or under the doctrine of equivalents.

**Thirteenth Affirmative Defense**  
**(Invalidity and/or Unenforceability of U.S. Patent No. 10,791,936)**

One or more claims of the '936 patent are invalid and/or unenforceable for failure to comply with one or more of the requirements for patentability set forth in Title 35 of the U.S. Code, including

§§ 101, 102, 103, 112, and 116 and/or invalid under any other ground provided by 35 U.S.C. § 282, and/or based on other judicially-created bases for invalidity or unenforceability.

**Fourteenth Affirmative Defense**  
**(Non-Infringement of U.S. Patent No. 10,791,936)**

Plaintiff has failed to aver any facts that support its allegations of infringement by the accused products. The accused products do not infringe any valid and enforceable claim of the '936 patent, either literally or under the doctrine of equivalents.

**Fifteenth Affirmative Defense**  
**(Prosecution History Estoppel)**

Plaintiff is estopped from arguing and has waived arguments that the claims of the '433, '519, '151, '152, '527, '609, and '936 patents cover the products described by virtue of amendments, positions, and arguments made to the USPTO when obtaining the asserted patents.

**Sixteenth Affirmative Defense**  
**(Failure to State a Claim)**

Plaintiff's Complaint fails to state a claim upon which relief can be granted.

**Seventeenth Affirmative Defense**  
**(Lack of Standing)**

Plaintiff does not have standing to assert claims for patent infringement under 35 U.S.C. § 271(a), (b), and (c).

**Eighteenth Affirmative Defense**  
**(Equitable Estoppel, Laches, Waiver, Acquiescence, and/or Unclean Hands)**

Plaintiff's claims for relief are barred by the doctrines of waiver, laches, acquiescence, unclean hands, and/or estoppel with respect to asserted claims of the '433, '519, '151, '152, '527, '609, and '936 patents because Plaintiff unreasonably delayed and misled 3Shape as to its intent not to enforce these patents against 3Shape after it learned, or through reasonable diligence should have learned about 3Shape's products, of its purported causes of action against 3Shape, and since such time 3Shape has

expended substantial amounts of time, money, and effort to build its business, brand and recognition of its name and products.

**Nineteenth Affirmative Defense**  
**(Covenant Not to Sue)**

Plaintiff has covenanted not to sue 3Shape on the asserted patents.

**Twentieth Affirmative Defense**  
**(License)**

Plaintiff’s claims for relief are barred with respect to asserted claims of the ’433, ’519, ’151, ’152, ’527, ’609, and ’936 patents to the extent the accused 3Shape products are expressly or impliedly licensed under these patents.

**Twenty-First Affirmative Defense**  
**(Patent Misuse)**

Plaintiff’s claims are barred, in whole or in part, by the doctrine of patent misuse.

**Twenty-Second Affirmative Defense**  
**(Unavailability of Relief – Bar to Damages, Marking, and Notice)**

Plaintiff’s claim for relief is barred, in whole or in part, because Plaintiff is not entitled to damages under 35 U.S.C. § 286, Plaintiff has failed to plead and meet the requirements of 35 U.S.C. § 287 on marking and notice, and Plaintiff has otherwise failed to show that it is entitled to any damages prior to the filing date of Plaintiff’s Complaint.

**Twenty-Third Affirmative Defense**  
**(Failure to Join an Indispensable Party)**

Plaintiff’s Complaint fails to join an indispensable party – namely, Defendants’ sister-company, 3Shape Inc.

**Twenty-Fourth Affirmative Defense**  
**(Inconvenient Venue)**

Pursuant to 28 U.S.C. § 1404, Plaintiff’s claims should be transferred to the District of Delaware for convenience and to promote judicial efficiency and economy, because Plaintiff has filed



seven separate lawsuits against Defendants in that district accusing the same products of infringement that are accused here.

**Twenty-Fifth Affirmative Defense**  
**(Patent Misuse and Unenforceability of U.S. Patent No. 10,728,519 and Asserted Family Members Due to Inequitable Conduct)**

One or more claims of the ’519, ’151, ’152 and/or ’433 patents are unenforceable under the doctrines of inequitable conduct and/or patent misuse at least because Align failed to comply with its duty of disclosure, candor, and good faith under 37 C.F.R. § 1.56 by not disclosing information material to the patentability of the ’519 patent and/or family members of the ’519 patent to the United States Patent and Trademark Office (herein, the “USPTO”) and subsequently asserted the ’519 patent and its family members against 3Shape in this litigation, attempting to enforce a knowingly invalid and/or unenforceable patent, as further alleged in Counts XXII-XXIV of 3Shape’s Counterclaims, all of which are fully incorporated by reference herein.

**Twenty-Sixth Affirmative Defense**  
**(Additional Defenses or Counterclaims)**

Defendants reserve all defenses available under the Federal Rules of Civil Procedure, the U.S. Patent laws, and at equity, as well as any additional defenses or counterclaims that discovery may reveal, including that Plaintiff has failed to aver any facts supporting the conclusion that it has suffered any irreparable injury or harm under 35 U.S.C. § 283, Plaintiff has failed to aver any facts supporting the conclusion that it has suffered any damages under 35 U.S.C. § 284, and that Plaintiff has failed to aver any facts supporting that this is an exceptional case and/or an award of attorney’s fees is appropriate under 35 U.S.C. § 285.

WHEREFORE, Defendants request that Plaintiff’s Complaint be dismissed with prejudice and that Defendants be awarded the costs of this action, their attorneys’ fees, and all other relief that this Court deems just and proper.

## **CONTINGENT COUNTERCLAIMS**

Subject to and only in the event the Court denies Defendants’ Motion, Defendants/Counterclaim-Plaintiffs hereby contingently submit the following counterclaims against Plaintiff/Counterclaim-Defendant Align.

### **PARTIES**

1. Counterclaim-Plaintiff 3Shape A/S (“3Shape A/S”) is a Danish corporation with a principal place of business at Holmens Kanal 7, 1060 Copenhagen K, Denmark.
2. Counterclaim-Plaintiff 3Shape Trios A/S (“3Shape Trios A/S”) is a Danish corporation with a principal place of business at Holmens Kanal 7, 1060 Copenhagen K, Denmark.
3. 3Shape A/S is the owner by assignment of the entire right, title and interest in and to U.S. Patent No. 10,905,333 (the “333 patent”) entitled, “3D intraoral scanner measuring fluorescence,” a copy of which is attached hereto as Exhibit 4.
4. 3Shape A/S is the owner by assignment of the entire right, title and interest in and to U.S. Patent No. 10,383,711 (the “711 patent”) entitled, “Focus scanning apparatus recording color,” a copy of which is attached hereto as Exhibit 5.
5. 3Shape A/S is the owner by assignment of the entire right, title and interest in and to U.S. Patent No. 10,097,815 (the “815 patent”) entitled, “Focus scanning apparatus,” a copy of which is attached hereto as Exhibit 6.
6. 3Shape A/S is the owner by assignment of the entire right, title and interest in and to U.S. Patent No. RE48,221 (the “221 patent”) entitled, “System with 3D user interface integration,” a copy of which is attached hereto as Exhibit 7.
7. 3Shape markets and sells industry-leading Trios intraoral scanners, including, in the United States, Trios 3 and Trios 4 (collectively with their predecessors, Trios and Trios Color, “Trios”).

8. The Trios scanners incorporate embodiments of the claimed technologies in the ’711, ’815, ’221, and ’333 patents (collectively, the “Asserted Counterclaim Patents”).

9. On information and belief, Align is a Delaware corporation with its principal place of business in San Jose, California.

10. On information and belief, Align makes, uses, sells and offers for sale in the United States and/or imports into the United States, the iTero Element, Element 2, Element Flex, Element 5D, Element 5D Plus, Element 5D Plus Lite, and Element Foundation (collectively, the “iTero Element” or “iTero Element Scanners”), all of which comprise at least a handheld intraoral 3D scanner/wand and a base unit including a PC.

11. 3Shape’s Trios and Align’s iTero Element scanners compete against each other in, at least, the market for scanners for orthodontic treatment.

#### **JURISDICTION AND VENUE**

12. 3Shape’s contingent counterclaims arise under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, the Lanham Act, 15 U.S.C. § 1125, and state laws.

13. This Court has original jurisdiction over the subject matter of 3Shape’s federal question counterclaims pursuant to 15 U.S.C. § 1121 and 28 U.S.C. §§ 1331, 1338, 2201, and 2202.

14. This Court has diversity jurisdiction over 3Shape’s federal and state law counterclaims under 28 U.S.C. § 1332(a) because Align is a citizen of a U.S. state(s) and 3Shape is a citizen of a foreign state, and the amount in controversy exceeds \$75,000.

15. This Court has supplemental jurisdiction over 3Shape’s counterclaims of business disparagement, unjust enrichment, tortious interference with prospective business relations, tortious interference with contractual relations, unfair competition, and fraudulent inducement pursuant to 28 U.S.C. § 1367.

16. This Court has personal jurisdiction over Align because Align has purposefully availed itself of the rights and privileges of this forum by bringing this civil action in this judicial district.

17. On information and belief, and as further described herein, Align has infringed and continues to infringe and/or contributorily infringe the Asserted Counterclaim Patents in Texas, which has led to foreseeable harm and injury to 3Shape. On information and belief, Align derives substantial revenue from the sale of infringing products distributed within Texas and/or expects or should reasonably expect its actions to have consequences in Texas. In addition, on information and belief, Align knowingly induces, and continues to knowingly induce, infringement of the Asserted Counterclaim Patents within Texas by offering for sale, selling, and/or contracting with others to market infringing products with the intent to facilitate infringing use of the products by others within Texas and by creating and/or disseminating product information and other materials providing instruction for infringing use.

18. Venue for these counterclaims is proper in this judicial district because Align brought this civil action in this judicial district and pursuant to 28 U.S.C. §§ 1391(b) and (c) and 1400(b).

## **FACTUAL BACKGROUND**

### **A. Introduction**

19. 3Shape is a pioneer developer of dental equipment and software for use by dental professionals and laboratories since 2004. In particular, 3Shape markets and sells Trios, along with a number of other dental hardware and software products.

20. Trios has now been named the best intraoral scanner in the industry for eight years in a row. Trios was also named the most accurate intraoral scanner in an independent American Dental Association study.

21. Trios has numerous operational advantages for dental professionals as well. The most important is that Trios is an open system scanner, integrated with many different providers of

restorative products and orthodontic treatments. Dental professionals can send scans directly from Trios to any provider that accepts STL files, the open industry standard file format. Trios’s open system provides patients and dental professionals freedom of choice and access to an open market for dental and orthodontic treatments.

22. 3Shape additionally develops, manufactures, and sells Dental System software for dental laboratories, which is also an open system. Dental System offers restorative workflows and enables dental labs to design, *e.g.*, dental prosthetics. Dental System accepts scan files from Trios and has accepted scan files from third party intraoral scanners, including Align’s iTero intraoral scanners, since 2008. (*See* Ex. 8.)

23. In addition to manufacturing iTero Element, Align is the dominant producer of clear aligners, with control of over 90 percent of the market – primarily under the Invisalign brand name. Align earns well over a billion dollars per year selling its Invisalign clear aligner products at high prices, with gross margins typically in excess of 75 percent.

24. As Align has repeatedly emphasized, dental professionals require a fast and accurate way to scan patients’ full mouths – the upper and lower jaws, teeth and bite – and to transfer that scan to a clear aligner manufacturer. There are only two viable scanners for this purpose: 3Shape’s Trios scanners and Align’s iTero Element scanners.

**B. 3Shape & Align’s Collaboration History**

25. In December 2015, Align and 3Shape Trios A/S entered into a contract (“the Scanner Agreement”), under which the parties worked together to build an interface so that dental professionals could send Trios scans into Align’s Invisalign workflow.

26. Align entered into the Scanner Agreement to increase Invisalign sales, as Align’s then-Chief Marketing Officer, Raphael Pascaud, testified under oath before the International Trade

Commission. Align also entered into the Scanner Agreement to access the broad group of dental practitioners using 3Shape’s technologically superior Trios scanner.

27. Prior to execution of the Scanner Agreement, Align [REDACTED]  
[REDACTED] That would have meant that [REDACTED]  
[REDACTED]  
[REDACTED] 3Shape refused Align’s [REDACTED] but the parties nonetheless subsequently entered into the Scanner Agreement.

28. The terms of the Scanner Agreement required 3Shape to [REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED] 3Shape actively promoted Invisalign in accordance with the Scanner Agreement to Align’s benefit.

29. On or about April 28, 2016, Align announced that 3Shape’s Trios intraoral scanners “will be available to use for Invisalign® case submissions upon completion of the final validation process expected in Q4 this year.” At the same time, Align announced a collaborative agreement with 3Shape “to enhance the existing STL export workflow with iTero® [including iTero Element] scanners and laboratory partners using 3Shape Dental System™ Software which will enable improved consistency for customers using the workflow.” (Ex. 9)

30. Subsequent to entering the Scanner Agreement, 3Shape’s Trios users were enabled to submit scans to initiate or continue Invisalign cases. Additionally, 3Shape worked to enhance its Dental System software for the benefit of Align and/or Align’s iTero users. 3Shape’s Dental System software already accepted STL files from Align’s iTero scanners prior to the Scanner Agreement and continues to accept STL files from Align’s iTero scanners to this day. (See Ex. 8.)

31. During this business relationship with 3Shape, Align’s Chief Executive Officer Joe Hogan became increasingly concerned that an increase in the popularity of the Trios scanner among dental professionals would lead to those dental professionals ordering clear aligners from Align’s rivals instead of Invisalign.

32. At a meeting between the parties in November 2016, [REDACTED]  
[REDACTED]  
[REDACTED]

33. Throughout 2017, including at the International Dental Show in March 2017, Mr. Pascaud continued to [REDACTED] 3Shape continued to refuse.

**C. Termination of the Scanner Agreement & Align’s Initial Lawsuits Against 3Shape**

34. On November 14, 2017, Align filed six patent infringement lawsuits alleging that 3Shape’s Trios intraoral scanners and Dental System software infringe Align’s patents. Four of these lawsuits were filed in the District of Delaware and two were brought before the International Trade Commission.<sup>2</sup>

35. These lawsuits collectively involved twenty-six patents, including the ’433 patent and family members of five other patents Align asserts in its Complaint here.

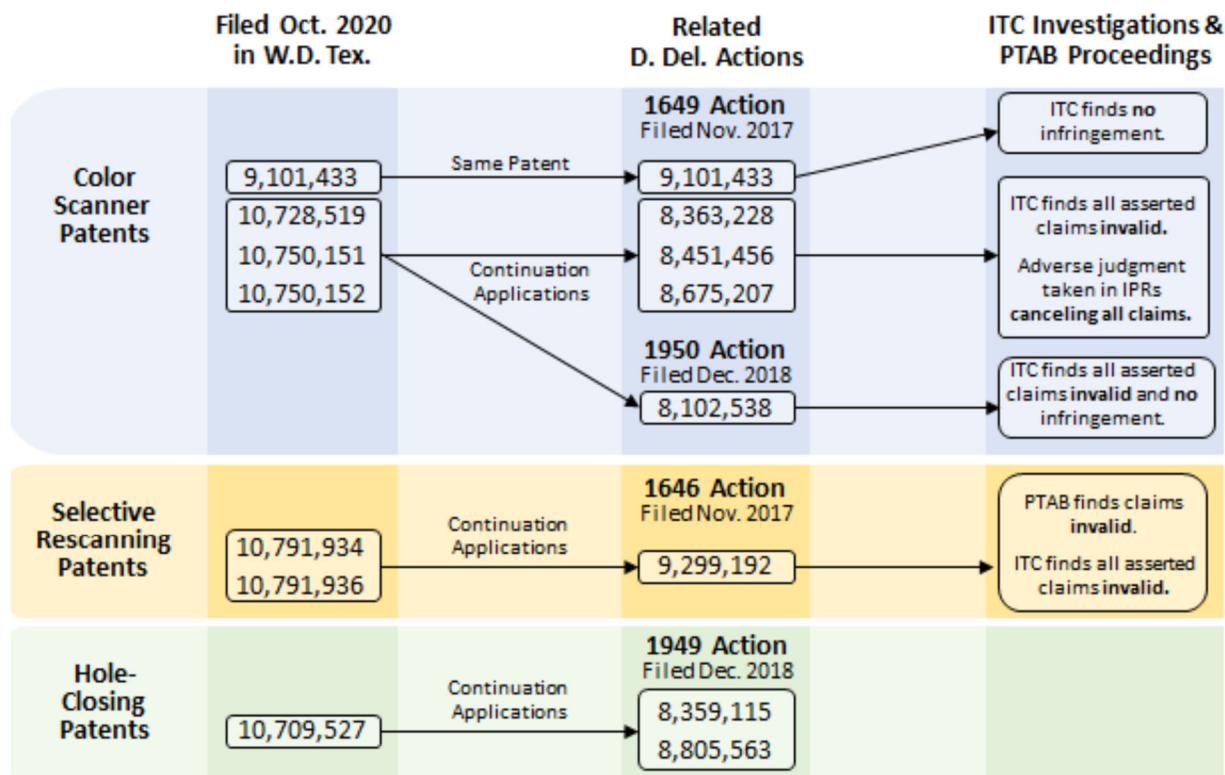
36. The ITC found, after a full investigation and evidentiary hearing that 3Shape does not infringe the ’433 patent. (*See Ex. 1.*) In fact, 3Shape was not found to infringe a single valid claim of any Align patent in either the 1090 or 1091 Investigations.

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<sup>2</sup> *See Align Tech. Inc. v. 3Shape A/S et al.*, C.A. No. 17-cv-01646-LPS (D. Del.) (the “1646 Action”); *Align Tech. Inc. v. 3Shape A/S et al.*, C.A. No. 17-cv-01647-LPS (D. Del.) (the “1647 Action”); *Align Tech. Inc. v. 3Shape A/S et al.*, 17-cv-01648-LPS (D. Del.) (the “1648 Action”); *Align Tech. Inc. v. 3Shape A/S et al.*, C.A. No. 17-cv-01649-LPS (D. Del.) (the “1649 Action”); *Certain Intraoral Scanners and Related Hardware and Software*, Inv. No. 337-TA-1090 (U.S.I.T.C.) (the “1090 Investigation”); *Certain Color Intraoral Scanners and Related Hardware and Software*, Inv. No. 337-TA-1091 (U.S.I.T.C.) (the “1091 Investigation”).

37. Align accused 3Shape’s Trios intraoral scanners of infringement in the complaints in all six of its November 14, 2017 lawsuits, including the 1090 and 1091 Investigations. In the following two years, Align filed three additional patent infringement lawsuits in the District of Delaware and a third investigation at the ITC.<sup>3</sup> Align once again accused 3Shape’s Trios intraoral scanners in all four of these complaints. And 3Shape once again prevailed at the ITC, this time in the 1144 Investigation.

38. All told, the ITC and/or Patent Trial and Appeal Board have each determined that family members of six of the seven patents asserted in the Complaint are invalid and/or not infringed, as illustrated in the below chart. (See Exs. 1, 2, 3.)



<sup>3</sup> See *Align Tech. Inc. v. 3Shape A/S et al.*, C.A. No. 18-cv-01949-LPS (D. Del.) (the “1949 Action”); *Align Tech. Inc. v. 3Shape A/S et al.*, C.A. No. 18-cv-01950-LPS (D. Del.) (the “1950 Action”); *Align Tech. Inc. v. 3Shape A/S et al.*, C.A. No. 19-cv-2098-LPS (D. Del.) (the “2098 Action”); *Certain Dental and Orthodontic Scanners and Software*, Inv. No. 337-TA-1144 (U.S.I.T.C.) (the “1144 Investigation”).



39. A month after launching its initial six cases on November 14, 2017, Align announced that it was unilaterally terminating the Scanner Agreement with 3Shape and closing the technical interoperability between Trios and Invisalign for new cases in the U.S., effective January 17, 2018. (Ex. 10.) Align followed through on its December 2017 press release, terminating the Scanner Agreement and closing the Trios-Invisalign interface in 2018 (albeit after January 17), and therefore, Trios scanners can no longer submit digital scans for Invisalign in the United States. (Ex. 12.) As a result of Align terminating the Scanner Agreement and closing the interface, 3Shape lost numerous Trios sales in the U.S. 3Shape was also required to unwind its contractually mandated active promotion of Invisalign, to 3Shape’s detriment.

40. Although the Scanner Agreement extends beyond the United States and Align unilaterally terminated the agreement in its entirety, Align only closed the Trios-Invisalign interface in the United States. In the rest of the world, where Align has a materially lower clear aligner market share, Align continues to accept scans from 3Shape Trios users despite its unilateral termination of the Scanner Agreement.

**D. The December 2017 Emails**

41. In December 2017, concurrent with its announcement that it would shortly terminate the Scanner Agreement and Trios-Invisalign interface, Align disseminated iTero Element promotional materials to Trios users who had submitted Invisalign cases digitally using a Trios intraoral scanner while the Trios-Invisalign interface was open. (Exs. 11, 12, 13.)

42. These promotional materials included a letter sent at least on December 18, 2017, to multiple 3Shape Trios users.

43. Align’s December 18, 2017 letter stated that “[d]ue to 3Shape’s infringing conduct and the resulting litigation, we terminated our Invisalign interoperability contract with 3Shape and will no

longer be able to accept digital scans for Invisalign treatment and/or retention cases from Trios scanners in the United States effective January 17, 2018.”

44. Align’s December 18, 2017 letter also included two offers:

First, eligible U.S. customers may purchase an iTero Element Scanner at the One-Time price of \$14,999, which includes one-year subscription & services (list price \$29,999) and a discount on Invisalign Full, Teen, and Assist PVS submitted cases through April 30, 2018.

Second, those eligible customers who choose not to purchase an iTero Element Scanner on the terms described above and who submitted at least one Invisalign Full, Teen, or Assist case using their TRIOS scanner on or after January 1, 2017 but before December 18, 2017 may elect to receive a discount on PVS submitted Invisalign clear aligner cases in 2018 through a PVS Offer. The details of this PVS Offer can be found on the Invisalign Doctor Site (IDS).

45. On information and belief, Align’s December 18, 2017 letter was widely disseminated to 3Shape Trios users in the United States.

46. As of December 18, 2017, the date of Align’s letter, 3Shape had never been found to infringe any Align patent or patent claim by any tribunal anywhere in the world. To date, 3Shape still has not been found to infringe any valid Align patent or patent claim.

#### **E. The Current Litigation**

47. The accused Trios, Trios 3, Trios 4, and Dental System software do not infringe any valid claim of any Align asserted patent, including the ’433, ’519, ’151, ’152, ’527, ’609, and ’936 patents.

48. Each of the patents asserted in the Complaint is invalid.

### **COUNT I (Declaratory Judgment of Invalidity and/or Unenforceability of U.S. Patent No. 9,101,433)**

49. Counterclaim-Plaintiffs restate and reallege each of the foregoing paragraphs 1-48 of the Counterclaims as if fully set forth herein.

50. 3Shape is entitled to a declaration that the asserted claims of the ’433 patent are invalid and/or unenforceable pursuant to at least 35 U.S.C. §§ 101, 102, 103, 112, and 116.

**COUNT II**  
**(Declaratory Judgment of Non-Infringement of U.S. Patent No. 9,101,433)**

51. Counterclaim-Plaintiffs restate and reallege each of the foregoing paragraphs 1-50 of the Counterclaims as if fully set forth herein.

52. 3Shape is entitled to a declaration that it does not infringe the asserted claims of the ’433 patent.

**COUNT III**  
**(Declaratory Judgment of Invalidity and/or Unenforceability of U.S. Patent No. 10,728,519)**

53. Counterclaim-Plaintiffs restate and reallege each of the foregoing paragraphs 1-52 of the Counterclaims as if fully set forth herein.

54. 3Shape is entitled to a declaration that the asserted claims of the ’519 patent are invalid and/or unenforceable pursuant to at least 35 U.S.C. §§ 101, 102, 103, 112, and 116.

**COUNT IV**  
**(Declaratory Judgment of Non-Infringement of U.S. Patent No. 10,728,519)**

55. Counterclaim-Plaintiffs restate and reallege each of the foregoing paragraphs 1-54 of the Counterclaims as if fully set forth herein.

56. 3Shape is entitled to a declaration that it does not infringe the asserted claims of the ’519 patent.

**COUNT V**  
**(Declaratory Judgment of Invalidity and/or Unenforceability of U.S. Patent No. 10,750,151)**

57. Counterclaim-Plaintiffs restate and reallege each of the foregoing paragraphs 1-56 of the Counterclaims as if fully set forth herein.

58. 3Shape is entitled to a declaration that the asserted claims of the ’151 patent are invalid and/or unenforceable pursuant to at least 35 U.S.C. §§ 101, 102, 103, 112, and 116.

**COUNT VI**  
**(Declaratory Judgment of Non-Infringement of U.S. Patent No. 10,750,151)**

59. Counterclaim-Plaintiffs restate and reallege each of the foregoing paragraphs 1-58 of the Counterclaims as if fully set forth herein.

60. 3Shape is entitled to a declaration that it does not infringe the asserted claims of the '151 patent.

**COUNT VII**  
**(Declaratory Judgment of Invalidity and/or Unenforceability of U.S. Patent No. 10,750,152)**

61. Counterclaim-Plaintiffs restate and reallege each of the foregoing paragraphs 1-60 of the Counterclaims as if fully set forth herein.

62. 3Shape is entitled to a declaration that the asserted claims of the '152 patent are invalid and/or unenforceable pursuant to at least 35 U.S.C. §§ 101, 102, 103, 112, and 116.

**COUNT VIII**  
**(Declaratory Judgment of Non-Infringement of U.S. Patent No. 10,750,152)**

63. Counterclaim-Plaintiffs restate and reallege each of the foregoing paragraphs 1-62 of the Counterclaims as if fully set forth herein.

64. 3Shape is entitled to a declaration that it does not infringe the asserted claims of the '152 patent.

**COUNT IX**  
**(Declaratory Judgment of Invalidity and/or Unenforceability of U.S. Patent No. 10,709,527)**

65. Counterclaim-Plaintiffs restate and reallege each of the foregoing paragraphs 1-64 of the Counterclaims as if fully set forth herein.

66. 3Shape is entitled to a declaration that the asserted claims of the '527 patent are invalid and/or unenforceable pursuant to at least 35 U.S.C. §§ 101, 102, 103, 112, and 116.

**COUNT X**  
**(Declaratory Judgment of Non-Infringement of U.S. Patent No. 10,709,527)**

67. Counterclaim-Plaintiffs restate and reallege each of the foregoing paragraphs 1-66 of the Counterclaims as if fully set forth herein.

68. 3Shape is entitled to a declaration that it does not infringe the asserted claims of the '527 patent.

**COUNT XI**  
**(Declaratory Judgment of Invalidity and/or Unenforceability of U.S. Patent No. 10,945,609)**

69. Counterclaim-Plaintiffs restate and reallege each of the foregoing paragraphs 1-68 of the Counterclaims as if fully set forth herein.

70. 3Shape is entitled to a declaration that the asserted claims of the '609 patent are invalid and/or unenforceable pursuant to at least 35 U.S.C. §§ 101, 102, 103, 112, and 116.

**COUNT XII**  
**(Declaratory Judgment of Non-Infringement of U.S. Patent No. 10,945,609)**

71. Counterclaim-Plaintiffs restate and reallege each of the foregoing paragraphs 1-70 of the Counterclaims as if fully set forth herein.

72. 3Shape is entitled to a declaration that it does not infringe the asserted claims of the '609 patent.

**COUNT XIII**  
**(Declaratory Judgment of Invalidity and/or Unenforceability of U.S. Patent No. 10,791,936)**

73. Counterclaim-Plaintiffs restate and reallege each of the foregoing paragraphs 1-72 of the Counterclaims as if fully set forth herein.

74. 3Shape is entitled to a declaration that the asserted claims of the '936 patent are invalid and/or unenforceable pursuant to at least 35 U.S.C. §§ 101, 102, 103, 112, and 116.

**COUNT XIV**  
**(Declaratory Judgment of Non-Infringement of U.S. Patent No. 10,791,936)**

75. Counterclaim-Plaintiffs restate and reallege each of the foregoing paragraphs 1-74 of the Counterclaims as if fully set forth herein.

76. 3Shape is entitled to a declaration that it does not infringe the asserted claims of the '936 patent.

**COUNTS XV-XX**

77. Counterclaim-Plaintiffs have removed Counts XV-XX from this amended pleading pursuant to the Court's August 9, 2021 order dismissing these claims.

**COUNT XXI**  
**(Fraudulent Inducement of Contract and/or Common Law Fraud)**

78. Counterclaim-Plaintiffs restate and reallege each of the foregoing paragraphs 1-77 of the Counterclaims as if fully set forth herein.

79. Prior to entering into the Scanner Agreement, Align made statements and representations concerning facts material to 3Shape's decision to enter into the Scanner Agreement.

80. For example, prior to entering into the Scanner Agreement, Align – through one or more of its officers, directors, agents, employees, and/or persons acting in concert or active participation with Align or on its behalf – including but not limited to Align C-suite or VP-level employees Joseph Hogan, Timothy Mack, Raphael Pascaud, and Avi Kopelman – communicated to 3Shape that 3Shape's products infringed Align's patents. One such instance occurred at the Chicago Dental Society Midwinter Meeting in 2013, where such communications were made by Mr. Mack and Mr. Kopelman to at least 3Shape's co-founder Tais Clausen. Similar communications were made at an October 2015 meeting between Align's CEO Joe Hogan and 3Shape's then-CEO Flemming Thorup.

81. Prior to the execution of the Scanner Agreement, Align representatives also insisted to 3Shape representatives that Align would not proceed with the Scanner Agreement, or the actual integration and validation of Trios scanners for Invisalign submission, due to these alleged

infringement concerns and until after these alleged infringement concerns were resolved. For example, Align executive Tim Mack and Align VP Srini Kaza made various such communications to 3Shape VP Allan Hyldal in or around 2013-2015, stating that Align’s alleged infringement concerns would need to be addressed prior to negotiating the Scanner Agreement. Mr. Hogan made a similar statement to Mr. Thorup at their October 2015 meeting.

82. In the months prior to the execution of the Scanner Agreement, Mr. Thorup contacted Align to ensure that Align’s alleged infringement concerns were addressed and resolved. Just weeks later, Align entered into the Scanner Agreement on or about December 31, 2015 and validated Trios for interoperability with Invisalign thereafter.

83. 3Shape reasonably and justifiably relied upon Align’s actions culminating in the entry into the Scanner Agreement and validation of 3Shape’s Trios scanners in believing that Align’s previous concerns based on alleged infringement were overcome.

84. After Align told 3Shape for years that it would not enter into a Scanner Agreement until after its infringement concerns were resolved, Align’s entering the Scanner Agreement reasonably conveyed that its alleged infringement concerns were in fact resolved, which was false when made and/or was made with reckless indifference to the truth.

85. Align represented to 3Shape that 3Shape could not obtain interoperability with Align’s Invisalign without entering the Scanner Agreement. On information and belief, Align did so knowing that it could and did permit interoperability in the absence of a formal contract or scanner agreement governing that interoperability.

86. Align’s representations were made with the intent to induce 3Shape to enter into the Scanner Agreement and/or promote sales of Align’s Invisalign clear aligners.

87. Align’s express and implied approval encouraged and required 3Shape to expend resources promoting Invisalign to the detriment of its other clear aligner partners, and to further

develop and make capital investments in the products Align accuses of infringement. For example, 3Shape promoted Invisalign on its own website and created another website to promote Invisalign as its preferred clear aligner to make it very simple for Trios users to connect to Invisalign. After Align terminated the Scanner Agreement and closed the Trios-Invisalign interface in the U.S., 3Shape was required, for example, to redesign its website (at a loss to 3Shape) to remove Invisalign as the preferred Trios clear aligner partner.

88. 3Shape also created various new printed marketing materials expressly listing Invisalign as the preferred Trios clear aligner partner. After Align terminated the Scanner Agreement and closed the Trios-Invisalign interface in the U.S., 3Shape was required to destroy all of this printed marketing material (at a loss to 3Shape) and create all new printed marketing material that no longer listed Invisalign as the preferred Trios clear aligner partner.

89. 3Shape also made extensive expenditures building, testing, validating, and maintaining the Trios to Invisalign interface and to further develop the interface between 3Shape’s Dental System software and Align’s iTero scanner.

90. Align’s aforementioned actions constitute a false representation that it no longer would assert claims of patent infringement against 3Shape after entering into the Scanner Agreement.

91. Align’s aforementioned actions constitute a false representation that 3Shape was required to enter into the Scanner Agreement to obtain interoperability between Trios and Invisalign.

92. Align entered into the Scanner Agreement knowing that it falsely represented it would not assert claims of patent infringement against 3Shape.

93. Align entered into the Scanner Agreement knowing that it falsely represented that the Scanner Agreement was required for interoperability between 3Shape’s Trios scanner and Align’s Invisalign.



94. Align’s intentional misrepresentations induced 3Shape to enter into the Scanner Agreement.

95. 3Shape reasonably relied upon Align’s false and intentional misrepresentations.

96. 3Shape suffered damages as a result of Align’s false and intentional misrepresentations and intentional inducement, including economic injury and actual damages, lost business opportunity, and profits across the United States.

97. Align’s actions constitute fraud at common law.

**COUNT XXII**  
**(Declaratory Judgment of Unenforceability of U.S. Patent No. 10,728,519 Due to Inequitable Conduct)**

98. Counterclaim-Plaintiffs restate and reallege each of the foregoing paragraphs 1-97 of the Counterclaims as if fully set forth herein.

99. All claims of the ’519 patent are unenforceable due to inequitable conduct.

100. On information and belief, during the prosecution of the ’519 patent, Align and its attorneys made affirmative misrepresentations of material fact, failed to disclose material information, and/or submitted false material information to the USPTO, with specific intent to deceive the USPTO resulting in the USPTO granting the ’519 patent.

101. For example, Align and its attorneys made false affirmative statements of material fact regarding the disclosures made in a prior art reference and failed to correct the ’519 patent examiner’s erroneous understanding of said prior art reference at least by failing to disclose material information to the examiner.

102. During the prosecution of the ’519 patent, the examiner rejected the then-pending claims in view of PCT Publication No. WO 00/08415 (hereinafter “Babayoff” and attached hereto as Ex. 15) in combination with U.S. Patent Publication No. 2002/0057438 (hereinafter “Decker”) in an office action dated June 19, 2019. Babayoff is the parent application to several other patents and

applications (the “Babayoff Family”), including U.S. Patent Nos. 8,638,447; 8,638,448; and 9,615,901 (the “Asserted Babayoff Family Patents”), owned and procured by Align and which Align has asserted against 3Shape in various litigations for over four years (including in the 1648 Action in Delaware and the 1090 Investigation at the ITC).

103. At least by virtue of ownership and prosecution of the Babayoff Family and extensive litigation of certain patent family members, Align and its attorneys had extensive familiarity with the disclosure of the Babayoff Family. For example, during the 1090 Investigation (in which the ALJ found 3Shape did not infringe the Asserted Babayoff Family Patents) Align and its attorneys relied upon the disclosures of the Babayoff Family, *e.g.*, in various briefings, arguments, and testimony, including in briefings which occurred prior to and during the prosecution of the ’519 patent.

104. During the course of prosecution of the ’519 patent, to overcome the examiner’s rejection in light of Babayoff and Decker, Align amended the pending claims in an Amendment dated September 19, 2019 to recite “an illumination unit configured to transmit a first array of incident light along a path toward the three-dimensional structure” and “a detector configured to measure intensity of each of a plurality of returned light that return along the path and from the three-dimensional structure.” Align and its attorneys characterized this amendment to be “the arrangement recited in claim 1 with illuminating and returning light passing through the same path.”

105. In the Amendment, Align and its attorneys argued “Babayoff in view of Decker does not disclose each and every element of the amended independent claims.” Align and its attorneys further argued that “since the Examiner has acknowledged that Babayoff alone does not disclose this element, the combination of Babayoff with Decker also fails to disclose this element.” The September 19, 2019 Amendment and Reply was signed by Align’s outside counsel, Charles Hagadorn, III.

106. On information and belief, Align and its attorneys knew that Babayoff disclosed the amendment limitations of “an illumination unit configured to transmit a first array of incident light

beams along a path toward the three-dimensional structure” and “a detector configured to measure intensity of each of a plurality of returned light that return along the path and from the three-dimensional structure.” For example, Babayoff discloses “an illumination unit for providing an array of incident light beams transmitted towards the structure along an optical path through said probing unit to generate illuminated spots on said portion” and “a detector having an array of sensing elements for measuring intensity of each of a plurality of light beams returning from said spots propagating through an optical path opposite to that of the incident light beams.” (Ex. 15 at 3:23-4:9.) The specification further explains that the incident and returned light beams are along the same optical path. (See Ex. 15 at 10:22-24) (“The light scatted from each of the light spots includes a beam travelling initially in the Z axis along the opposite direction of the optical path traveled by the incident light beams.”) As such, Babayoff described the added “illumination unit” and “detector” limitations recited in the amended claims of the ’519 patent contrary to the statements made by Align and its attorneys. These disclosures of Babayoff appear in the specifications of patents and applications throughout the Babayoff Family.

107. During Align’s own claim construction briefing in the 1090 ITC, which was filed on May 4, 2018 (prior to the filing of the application of the ’519 patent), Align and its attorneys highlighted the fact that the Babayoff Family members describe “an illumination unit for providing an array of incident light beams transmitted...along an optical path” and returned light beams “along the opposite direction of the optical path traveled by the incident light beams.”

108. Beginning in March 2017 and during the course of the 1090 Investigation involving the Asserted Babayoff Family Patents and the prosecution of the ’519 Patent, Align’s outside counsel, Mr. Hagadorn, also prosecuted at least one member of the Babayoff Family (U.S. App. Serial No. 15/468,812). On information and belief, Mr. Hagadorn knew the Babayoff Family discloses “illuminating and returning light passing through the same path.”

109. On information and belief, Align and its attorneys purposefully and knowingly misled the examiner by affirmatively stating that Babayoff and Decker did not disclose the claims as amended – which added the “illumination unit” and “detector” limitations – despite Align and its attorneys knowing that Babayoff disclosed such limitations. On information and belief, Align and its attorneys did so knowing and intending the same to materially impact the examiner’s decision to allow the ’519 patent and to deceive the USPTO.

110. Align and its attorneys failed to disclose statements made in litigation (including, *e.g.*, during claim construction in the 1090 ITC) which characterize the Babayoff Family as describing “illuminating and returning light passing through the same path.” For example, Align and its attorneys failed to disclose the 1090 ITC or any materials therefrom during the prosecution of the ’519 patent. On information and belief these materials would have materially impacted the prosecution of the ’519 patent and were withheld with intent to deceive the USPTO.

111. Align and its attorneys knew that an appropriate and accurate understanding of Babayoff’s disclosure was material to prosecution of the ’519 patent.

112. On information and belief, Align and its attorneys knew that its mischaracterization of Babayoff during the prosecution of the ’519 patent contradicted Align’s statements made during litigation the Asserted Babayoff Family Patents.

113. On information and belief, Align and its attorneys knew that disclosing the existence of litigation of the Asserted Babayoff Patents and documents, testimony, and arguments characterizing the Babayoff Family made therein would have materially impacted the prosecution of the ’519 patent and the allowance of the claims of the ’519 patent.

114. Align’s affirmative misrepresentations regarding Babayoff constitute a breach of its duty of disclosure, candor, and good faith under 37 C.F.R. § 1.56 to disclose information material to patentability to the USPTO.

115. Align’s failure to disclose the 1090 Investigation and characterizations of the Babayoff Family before the ITC and District Court to the USPTO constitute a breach of its duty of disclosure, candor, and good faith under 37 C.F.R. § 1.56 to disclose information material to patentability to the USPTO.

116. On information and belief, Align made additional false affirmative statements during the prosecution of the ’519 patent. For example, on information and belief Align made assertions during the 1090 Investigation that were contradictory to assertions made by Align and its attorneys to the examiner of the application leading to the ’519 patent. Align’s failure to disclose the 1090 Investigation and the representations made by Align during the 1090 Investigation constitutes a breach of Align’s duty of disclosure, candor, and good faith under 37 C.F.R. § 1.56 to disclose information material to patentability to the USPTO.

117. Align also breached its duty of candor by burying material information in numerous transmittal letters and Information Disclosure Statements submitted during the prosecution of the ’519 Patent.

118. For example, Align and its attorneys failed to disclose reissued patents in the Babayoff Family that had substantially similar claims to those of the ’519 patent in a way that reasonably called the reissued patents or the material portions thereof to the examiner’s attention. Align and its attorneys did so despite being expressly informed by the examiner in the June 1, 2020 Notice of Allowance for the ’519 Patent that “[a]n applicant’s duty of disclosure of material information is not satisfied by presenting a patent examiner with ‘a mountain of largely irrelevant data from which he is presumed to have been able, with his expertise and with adequate time, to have found the critical data’ and stating that “[b]y initialing [the applicant’s submitted disclosures], Examiner is merely acknowledging the submission of the cited references and indicating that only a cursory review has been made.”

119. During previous litigation (initiated in November 2017 and heard by the ITC in 2018 – prior to the filing and prosecution of the ’519 patent), between Align and 3Shape, Align asserted the ’433 patent (asserted here) and three other Color Scanning Patent Family members – U.S. Patent Nos. 8,363,228; 8,451,456; and 8,675,207. These patents were asserted both in the 1091 Investigation and the 1949 Action.

120. As part of its response to Align’s litigation, 3Shape initiated IPR proceedings before the USPTO against the ’228, ’451, and ’207 patents, including filing six IPR petitions.

121. On February 7, 2020, Align requested adverse judgment in all six IPRs and the PTAB terminated all six on February 12, 2020.

122. The same day Align requested adverse judgment and during the prosecution of the ’519 patent, Align filed three reissue applications for the ’228, ’451, and ’207 patents. (U.S. Application Nos. 16/784,493, 16/784,501, and 16/784,515 (the “Reissue Color Scanning Applications”).)

123. The Reissue Color Scanning Applications have substantially similar claims to those of the ’519 patent.

124. Despite filing the applications for the Reissue Color Scanning Applications during the prosecution of the ’519 patent, Align and its attorneys failed to disclose them in a way that would reasonably call the patents to the examiner’s attention or which highlighted the substantial similarity of the claims of the Reissue Color Scanning Applications to those then pending in the ’519 patent prosecution.

125. On information and belief, Align and its attorneys knew the claims of the Reissue Color Scanning Applications to be substantially similar to those of the ’519 patent and that the examiner had not considered the claims.

126. On information and belief, Align and its attorneys knew the events leading up to the filing of the Reissue Color Scanning Applications were material to the '519 patent and would have caused the examiner to reject the claims then-pending in the '519 patent prosecution.

127. Align's failure to adequately disclose the Reissue Color Scanning Applications and the events leading up to their filing and failure to specifically call the examiner's attention to the Reissue Color Scanning Applications is a breach of Align's duty of disclosure, candor, and good faith under 37 C.F.R. § 1.56 to disclose information material to patentability to the USPTO.

128. Align buried additional material information and disclosures that would have adversely affected Align's prosecution of the issued claims of the '519 patent.

129. For example, on information and belief, Align and its attorneys knew information from the complex prosecution histories of the families and litigation between the parties, including but not limited to adverse prior art, reissue applications, terminal disclaimers, and District Court, ITC and PTAB litigation, were material to the then-pending claims of the '519 patent. On information and belief, Align and its attorneys withheld material information from the examiner by burying these references in the Information Disclosure Statements and various other transmittals in bad faith. Align and its attorneys were aware or should have been aware they had not complied with their duty of candor at least, *e.g.*, due to the express statements made by the examiner in the November 4, 2019 and June 1, 2020 Notice of Allowances issued during the prosecution of the '519 patent.

130. Align's burying of material information in the Information Disclosure Statement is a breach of Align's duty of disclosure, candor, and good faith under 37 C.F.R. § 1.56 to disclose information material to patentability to the USPTO.

131. On information and belief, Align committed the above-described misconduct, including by making affirmative misrepresentations of material facts and omissions and failing to adequately

disclose material information to the USPTO during the course of prosecution of the ’519 patent and did so with the specific intent to deceive the USPTO and receive an issued patent.

132. The claims of the ’519 patent would not have been allowed but for Align’s misconduct.

**COUNT XXIII**  
**(Declaratory Judgment of Unenforceability of U.S. Patent No. 10,750,151 Due to Inequitable Conduct)**

133. Counterclaim-Plaintiffs restate and reallege each of the foregoing paragraphs 1-132 of the Counterclaims as if fully set forth herein.

134. 3Shape is entitled to a declaration that the asserted claims of the ’151 patent are unenforceable due to inequitable conduct that occurred during the prosecution of the ’151 patent.

135. During the prosecution of the ’151 patent, Align failed to adequately disclose material information to the USPTO and breached its duty of candor and good faith in an effort to deceive the USPTO and receive an issued patent.

136. On information and belief, Align buried material information and disclosures that could have adversely affected Align’s application of the ’151 patent. Align and its attorneys did so despite being expressly informed by the examiner in the July 6, 2020 Notice of Allowance for the ’151 Patent that “An applicant’s duty of disclosure of material information is not satisfied by presenting a patent examiner with ‘a mountain of largely irrelevant data from which he is presumed to have been able, with his expertise and with adequate time, to have found the critical data’ and states “[b]y initialing [the applicant’s submitted disclosures], Examiner is merely acknowledging the submission of the cited references and indicating that only a cursory review has been made.”

137. For example, on information and belief, Align and its attorneys knew information from the complex prosecution histories of the families, including but not limited to adverse prior art, reissue applications, and terminal disclaimers, were material to the then-pending claims of the ’151 patent.



138. On information and belief, Align and its attorneys buried these references in the Information Disclosure Statement in bad faith.

139. Align’s burying of material information in the Information Disclosure Statement is a breach of Align’s duty of disclosure, candor, and good faith under 37 C.F.R. § 1.56 to disclose information material to patentability to the USPTO.

140. On information and belief, Align and its attorneys failed to adequately disclose this material information with the specific intent to deceive the USPTO and receive an issued patent and the claims of the patent would not have been allowed but for Align’s misconduct.

141. On information and belief, the claims of the ’151 patent are also unenforceable under the doctrine of infectious unenforceability due to Align’s inequitable conduct associated with the ’519 patent, as detailed in Count XXII, at least because the inequitable conduct associated with the ’519 patent bears an immediate and necessary relation to the enforcement of the ’151 patent.

**COUNT XXIV**  
**(Declaratory Judgment of Unenforceability of U.S. Patent No. 10,750,152 Due to Inequitable Conduct)**

142. Counterclaim-Plaintiffs restate and reallege each of the foregoing paragraphs 1-141 of the Counterclaims as if fully set forth herein.

143. 3Shape is entitled to a declaration that the asserted claims of the ’152 patent are unenforceable due to inequitable conduct that occurred during the prosecution of the ’152 patent.

144. During the prosecution of the ’152 patent, Align failed to adequately disclose material information to the USPTO and breached its duty of candor and good faith in an effort to deceive the USPTO and receive an issued patent.

145. On information and belief, Align buried material information and disclosures that could have adversely affected Align’s application of the ’152 patent. Align and its attorneys did so despite being expressly informed by the examiner in the June 23, 2020 Notice of Allowance for the ’151 Patent

that “An applicant’s duty of disclosure of material information is not satisfied by presenting a patent examiner with ‘a mountain of largely irrelevant data from which he is presumed to have been able, with his expertise and with adequate time, to have found the critical data” and states “[b]y initialing [the applicant’s submitted disclosures], Examiner is merely acknowledging the submission of the cited references and indicating that only a cursory review has been made.”

146. For example, on information and belief, Align and its attorneys knew information from the complex prosecution histories of the families, including but not limited to adverse prior art, reissue applications, and terminal disclaimers, were material to the then-pending claims of the ’152 patent.

147. On information and belief, Align and its attorneys buried these references in the Information Disclosure Statement in bad faith.

148. Align’s burying of material information in the Information Disclosure Statement is a breach of Align’s duty of disclosure, candor, and good faith under 37 C.F.R. § 1.56 to disclose information material to patentability to the USPTO.

149. On information and belief, Align and its attorneys failed to adequately disclose this material information with the specific intent to deceive the USPTO and receive an issued patent and the claims of the patent would not have been allowed but for Align’s misconduct.

150. On information and belief, the claims of the ’152 patent are also unenforceable under the doctrine of infectious unenforceability due to Align’s inequitable conduct associated with the ’519 patent, as detailed in Count XXII, at least because the inequitable conduct associated with the ’519 patent bears an immediate and necessary relation to the enforcement of the ’151 patent.

**COUNT XXV**  
**(Infringement of U.S. Patent No. 10,097,815)**

151. Counterclaim-Plaintiffs restate and reallege each of the foregoing paragraphs 1-150 of the Counterclaims as if fully set forth herein.

152. This cause of action arises under the patent laws of the United States, and in particular, 35 U.S.C. §§271, *et seq.*

153. The ’815 patent, entitled “Focus scanning apparatus,” was duly and lawfully issued by the United States Patent and Trademark Office (“USPTO”) on October 9, 2018, to listed inventors Rune Fisker, Henrik Öjelund, Rasmus Kjær, Mike van der Poel, Arish A. Qazi, and Karl-Josef Hollenbeck. 3Shape A/S is the owner by assignment of all right, title, and interest in and to the ’815 patent.

154. The ’815 patent discloses inventions relating to a scanner for determining the 3D geometry of the surface of an object. In particular, the ’815 patent describes the use of motion sensors (*e.g.*, accelerometers and/or gyros) to (1) measure motion in three dimensions in the scanner to assist with stitching or registering partial scans together or (2) remotely control the 3D surface geometry of the object displayed on the computer screen. Using the motion sensors for remote control of the 3D surface geometry on the display is particularly advantageous for hygienic considerations to avoid contamination from using other hand-operated input devices.

155. Align makes, uses, offers to sell, sells, imports, promotes and/or demonstrates versions of its iTero Element Scanners, including the wand, cart, and/or related software, and other related products in the United States.

156. 3Shape has good cause to believe that Align generally monitors 3Shape’s patents and patent prosecution, at least because Align has filed IPRs on 3Shape patents before they were asserted in litigation or subject to any notice letter. Thus, on information and belief, Align possesses knowledge of, and is aware of, the ’815 patent.

157. Align has been and is now directly infringing, literally and/or under the doctrine of equivalents, at least claim 1 of the ’815 patent.

158. By way of illustration only, the iTero Element Scanners meet each element of claim 1 of the '815 patent.

159. The iTero Element Scanners are each “[a] scanner for determining the 3D geometry of at least a part of the surface of an object.” That scanner comprises “[1] at least one camera accommodating an array of sensor elements, [2] a light source for generating a probe light, [3] an optical system for transmitting the probe light towards the object along an optical path thereby illuminating at least a part of the object with said probe light and for transmitting at least a part of the light returned from the object to the camera, said optical system comprising: [1] a focus element for focusing at least a part of the probe light on the object; and [2] a translation stage for adjusting and controlling a position of the focus element along the optical path for varying a position of at least the part of the probe light as focused on the object, and [3] one or more built-in motion sensors which are configured to yield data for: [1] remotely controlling an image displayed on a display based on acquired scan data, or [2] stitching or registering partial scans to each other.” (Ex. 6 at col. 37 ll. 17-37.)

160. Public documentation illustrates how the iTero Element Scanners satisfy all elements of exemplary claim 1 of the '815 patent. By way of example only, the user manuals, brochure, product review, and training video below show that the iTero Element Scanners contain the infringing functionality. For example, the iTero Element Scanners determine the 3D geometry of the surface of an object using a color image sensor and optical laser scanning.

## Proven Imaging Precision.

The iTero® Intraoral Scanner is synonymous with high precision. Its parallel confocal imaging technology uses optical and laser scanning to achieve high precision and accuracy without powder or complicated hovering.

(iTero Element Brochure for General Practitioners at 2 (*available at*

<https://www.aligntech.com/documents/iTero-Element-Brochure-For-General-Practitioners.pdf>.)

### SCAN IN COLOR

Color scanning gives you a significant leap forward in visualization. The color sensor is integrated in iTero Element, and the patented dual-aperture lens system is designed to simultaneously capture 2D images in color with highly accurate 3D laser scanning. Color scanning can make it easier to immediately distinguish between gingival and tooth structures for a more precise clinical evaluation.

(*Id.* at 4.) In particular, the laser light used for the 3D laser scanning is generated from a 680nm red laser light.

## Hardware Specifications

ITEM	DESCRIPTION
Monitor	19" monitor
Scanner	Scanner emits red laser light (680nm Class 1) as well as white LED emissions.

(iTero Element Operation Manual at 17 (*available at* <https://storage-iTero-production-us.s3.amazonaws.com/download/en-us/iTero-Element-Operation-Manual.pdf>).)

161. Further, on information and belief, the red laser illuminates the object by being transmitted through an optical system that includes a focus element for focusing the laser on the object and a translation stage for the focusing element to vary the focus position of the probe light.



(Perry Jones, *The iTero optical scanner for use with Invisalign: A descriptive review* at 5 (*available at* [https://dentalacademyofce.com/courses/2223/PDF/1202CEIjones\\_web\\_rev.pdf](https://dentalacademyofce.com/courses/2223/PDF/1202CEIjones_web_rev.pdf)).) As illustrated above, the laser light is focused to different focus planes, which on information and belief, is accomplished by translating a focus element in the iTero Element Scanners. (*See id.*)

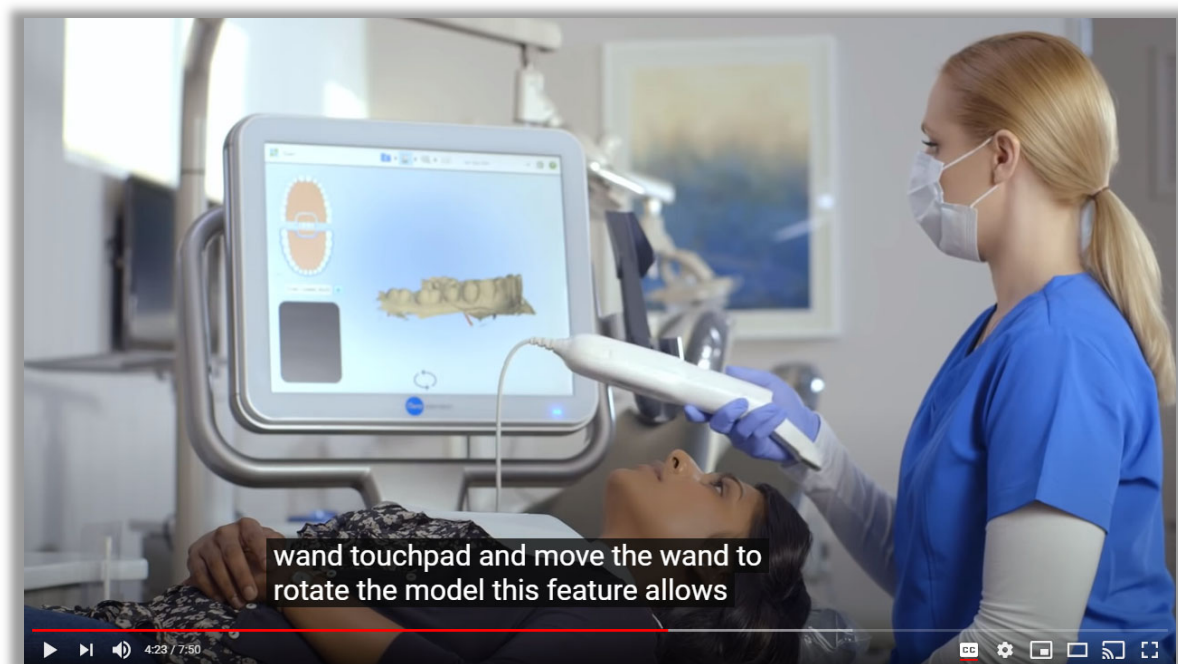
162. The iTero Element Scanners further include a built-in motion sensor (gyro) that is configured to remotely control the 3D surface model displayed on the screen generated from the scanner.



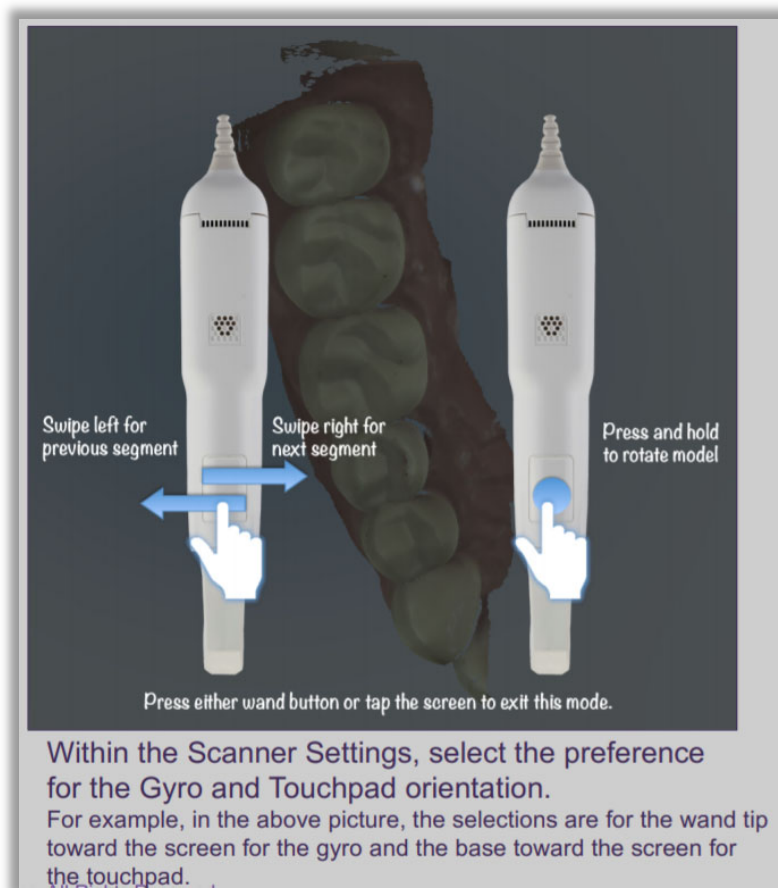
### ADVANCED WAND FEATURES

The redesigned wand features built-in controls, including side buttons and touchpad for user interface control. Integrated gyro technology lets you rotate models on screen. Plug and play wand cable quickly connects and disconnects to the base unit. And the patent pending ITO defogging system defogs instantly without needing air or extended warming.

(iTero Element Brochure for General Practitioners at 3.)



(iTero Element® Orthodontic Training Video (*available at <https://youtu.be/hDzBjbqD-KI?t=263>*).)



(iTero Element Intraoral Scanner Orthodontic Training Guidebook at 22 (May 2018) (*available at* <https://storagy-iTero-production-us.s3.amazonaws.com/download/en-us/iTero-Element-Ortho-Guidebook.pdf>).

163. Further, upon information and belief, the built-in motion sensor in the iTero Element is used to help in stitching and/or registering scans together. For example, the iTero Element is able to adapt to changes in positioning and stitch together images for rendering in the correct order.



SCAN IN MOTION

Continuous scanning design lets you scan in motion—eliminating the need to click each time you want to capture a scan. The software automatically detects and repositions scanning start and stop points when you move to a new scanning position within the scanned segment.

And while you are scanning, iTero Element is engineered to simultaneously process the scan. It automatically stitches together images for rendering in the correct order, adapts to changes in positioning, and detects and removes soft tissue. Capture everything. And view exactly what you need to see.

(iTero Element Brochure for General Practitioners at 4.)

164. Align thus directly infringes, literally and/or under the doctrine of equivalents, at least claim 1 of the '815 patent.

165. On information and belief, Align has directly infringed and continues to directly infringe the '815 patent including by making, selling, offering for sale in the United States, and importing into the United States the iTero Element Scanners.

166. Align also actively induces and has induced infringement of the '815 patent under 35 U.S.C. §271(b). 3Shape has good cause to believe that Align generally monitors 3Shape's patents and patent prosecution, at least because Align has filed IPRs on 3Shape patents before they were asserted in litigation or subject to any notice letter. Thus, on information and belief, Align has knowledge of and is aware of the '815 patent.

167. Align encouraged and facilitated infringement with specific intent by, for example, training its customers to use the iTero Element Scanners in a manner that infringes at least one claim of the '815 patent, promoting the use of the iTero Element Scanners in a way that infringes at least one

claim of the '815 patent to Align's customers, and disseminating promotional and marketing material and product literature to those customers encouraging use of the iTero Element Scanners in a manner that infringes at least one claim of the '815 patent.

168. Align's customers for the iTero Element Scanners directly infringe the '815 patent by making, using, selling, offering for sale, and/or importing the iTero Element Scanners.

169. Align has been and is now contributing to the infringement of one or more claims of the '815 patent under 35 U.S.C. §271(c).

170. Align has actively, knowingly, and intentionally contributed and continues to actively, knowingly, and intentionally contribute to the infringement of the '815 patent by selling or offering to sell, and continuing to sell or offer for sale the iTero Element Scanners within the United States and/or by importing the iTero Element Scanners into the United States with knowledge that the infringing technology in the iTero Element Scanners is especially made and/or especially adapted for use in infringement of the '815 patent, is a material part of the patented invention, and is not a staple article or commodity of commerce suitable for substantial non-infringing use and with knowledge that others including, but not limited to, resellers, distributors, customers, dentists, orthodontists, dental and orthodontic labs, and/or other end users of the iTero Element Scanners do not have any substantial noninfringing uses. Align has such knowledge at least because the claimed features of the '815 patent are used by others including, but not limited to resellers, distributors, customers, dentists, orthodontists, dental and orthodontic labs, and/or other end users of iTero Element Scanners.

171. Align has willfully infringed the '815 patent. On information and belief, Align has known of the '815 patent and has continued to infringe the patent in an egregious and wanton manner that Align knew or should have known amounted to infringement of the patent.

172. Align's acts of infringement have injured and damaged 3Shape and will continue to injure and damage 3Shape.

173. Align’s actions have caused 3Shape to suffer irreparable harm resulting from the loss of its lawful patent rights and the loss of its ability to exclude others from the market. On information and belief, Align will continue these infringing acts unless enjoined by this court.

**COUNT XXVI**  
**(Infringement of U.S. Patent No. 10,383,711)**

174. Counterclaim-Plaintiffs restate and reallege each of the foregoing paragraphs 1-173 of the Counterclaims as if fully set forth herein.

175. This cause of action arises under the patent laws of the United States, and in particular, 35 U.S.C. §§271, *et seq.*

176. The ’711 patent, entitled “Focus scanning apparatus recording color,” was duly and lawfully issued by the United States Patent and Trademark Office (“USPTO”) on August 20, 2019, to listed inventors Bo Esbech, Christian Romer Rosberg, Mike van der Poel, Rasmus Kjær, Michael Vinther, and Karl-Josef Hollenbeck. 3Shape A/S is the owner by assignment of all right, title, and interest in and to the ’711 patent.

177. The ’711 patent discloses inventions relating to a scanner for recording surface geometry and color of an object where the surface geometry and color are captured using the same color image sensor. By using a color image sensor to capture surface geometry and color, the scanner avoids the need to use two image sensors, one to capture surface geometry and one to capture color. Further, the ’711 patent discloses using a multichromatic light source (*e.g.*, white light) in conjunction with the color image sensor to capture more realistic surface color than the synthetic color captured using sequential colored illuminations. The ’711 patent further discloses that its scanner generates the surface geometry and color by processing the captured 2D images using blocks of image sensor pixels.

178. Align makes, uses, offers to sell, sells, imports, promotes and/or demonstrates versions of is iTero Element Scanners, including the wand, cart, and/or related software, and other related products in the United States.

179. 3Shape has good cause to believe that Align generally monitors 3Shape’s patents and patent prosecution, at least because Align has filed IPRs on 3Shape patents before they were asserted in litigation or subject to any notice letter. Thus, on information and belief, Align possesses knowledge of, and is aware of, the ’711 patent.

180. Align has been and is now directly infringing, literally and/or under the doctrine of equivalents, at least claim 1 of the ’711 patent.

181. By way of illustration only, the iTero Element Scanners meet each element of claim 1 of the ’711 patent.

182. The iTero Element Scanners are each “[a] scanner system for recording surface geometry and surface color of an object.” That scanner system comprises “[1] a multichromatic light source configured to provide a multichromatic probe light for illumination of the object, [2] color image sensor comprising an array of image sensor pixels to capture one or more 2D images of light received from the object, the color image sensor comprising a color filter array, and [3] a data processing system configured to derive surface geometry information for a first set of image pixels within a block of the image sensor pixels from a series of 2D images recorded by the color image sensor, [4] the data processing system further configured to derive surface color information for a second set of image pixels within the block of the image sensor pixels from at least one 2D image recorded by the color image sensor, wherein the surface color information is obtained by demosaicing the second set of the image sensor pixels, [5] wherein the first set of the image sensor pixels is different from the second set of the image sensor pixels.” (Ex. 5 at col. 19 ll. 44-65.)

183. Public documentation illustrates how the iTero Element Scanners satisfy all elements of exemplary claim 1 of the ’711 patent. By way of example only, the user manual and brochure below show that the iTero Element Scanners contain the infringing functionality. The iTero Element Scanners are scanner systems that record surface geometry and surface color using a color image sensor.

### SCAN IN COLOR

Color scanning gives you a significant leap forward in visualization. The color sensor is integrated in iTero Element, and the patented dual-aperture lens system is designed to simultaneously capture 2D images in color with highly accurate 3D laser scanning. Color scanning can make it easier to immediately distinguish between gingival and tooth structures for a more precise clinical evaluation.

(iTero Element Brochure for General Practitioners at 4 (*available at*

<https://www.aligntech.com/documents/iTero-Element-Brochure-For-General-Practitioners.pdf>.)

184. The iTero Element Scanners use this color image sensor to capture 2D images at a rate of 6,000 frames per second.

6,000

FRAMES PER SECOND

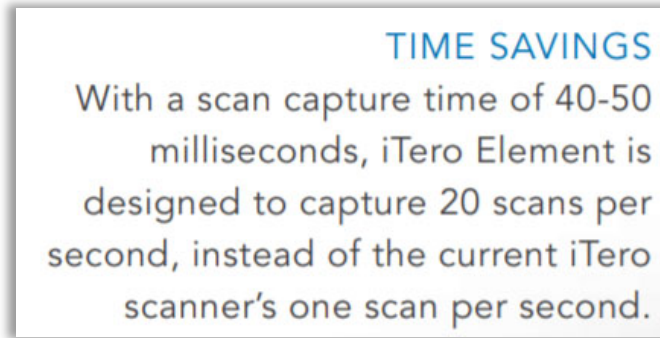
iTero Element is engineered to capture 6,000 frames per second—significantly faster than the current iTero’s 800 frames per second.

20X

FASTER SPEED

iTero Element image sensor is designed to enable 20X faster scan speed versus the current iTero scanner.

(*Id.* at 2.) Further, the iTero Element Scanners capture 20 scans per second, which means that 300 2D images are captured in a scan.



(*Id.* at 3.)

185. Further, on information and belief, the iTero Element Scanners use a multichromatic light source to record surface color of the object being scanned. For example, the iTero Element Scanner includes white LEDs.

Hardware Specifications	
ITEM	DESCRIPTION
Monitor	19" monitor
Scanner	Scanner emits red laser light (680nm Class 1) as well as white LED emissions.

(iTero Element Operation Manual at 17 (*available at* <https://storagy-iTero-production-us.s3.amazonaws.com/download/en-us/iTero-Element-Operation-Manual.pdf>).)

186. The iTero Element Scanners further use a 680nm red laser light to record surface geometry using the color image sensor. (*See id.*; *see also* iTero Element Brochure for General Practitioners at 4 (color image sensor is used to “simultaneously capture 2D images in color with highly accurate 3D laser scanning”).) On information and belief, the iTero Element scanners derive the surface geometry and the surface color using different sets of image pixels within a block of image sensor pixels.

187. Align thus directly infringes, literally and/or under the doctrine of equivalents, at least claim 1 of the '711 patent.

188. On information and belief, Align has directly infringed and continues to directly infringe the '711 patent including by making, selling, offering for sale in the United States, and importing into the United States the iTero Element Scanners.

189. Align also actively induces and has induced infringement of the '711 patent under 35 U.S.C. §271(b). 3Shape has good cause to believe that Align generally monitors 3Shape's patents and patent prosecution, at least because Align has filed IPRs on 3Shape patents before they were asserted in litigation or subject to any notice letter. Thus, on information and belief, Align has knowledge of and is aware of the '711 patent.

190. Align encouraged and facilitated infringement with specific intent by, for example, training its customers to use the iTero Element Scanners in a manner that infringes at least one claim of the '711 patent, promoting the use of the iTero Element Scanners in a way that infringes at least one claim of the '711 patent to Align's customers, and disseminating promotional and marketing material and product literature to those customers encouraging use of the iTero Element Scanners in a manner that infringes at least one claim of the '711 patent.

191. Align's customers for the iTero Element Scanners directly infringe the '711 patent by making, using, selling, offering for sale, and/or importing the iTero Element Scanners.

192. Align has been and is now contributing to the infringement of the '711 patent under 35 U.S.C. §271(c).

193. Align has actively, knowingly, and intentionally contributed and continues to actively, knowingly, and intentionally contribute to the infringement of the '711 patent by selling or offering to sell, and continuing to sell or offer for sale the iTero Element Scanners within the United States and/or by importing the iTero Element Scanners into the United States with knowledge that the infringing technology in the iTero Element Scanners is especially made and/or especially adapted for use in infringement of the '711 patent, is a material part of the patented invention, and is not a staple article or

commodity of commerce suitable for substantial non-infringing use, and with knowledge that others including, but not limited to, resellers, distributors, customers, dentists, orthodontists, dental and orthodontic labs, and/or other end users of the iTero Element Scanners do not have any substantial noninfringing uses. Align has such knowledge at least because the claimed features of the ’711 patent are used by others including, but not limited to resellers, distributors, customers, dentists, orthodontists, dental and orthodontic labs, and/or other end users of the iTero Elements Scanners.

194. Align has willfully infringed the ’711 patent. On information and belief, Align has known of the ’711 patent and has continued to infringe the patent in an egregious and wanton manner that Align knew or should have known amounted to infringement of the patent.

195. Align’s acts of infringement have injured and damaged 3Shape and will continue to injure and damage 3Shape.

196. Align’s actions have caused 3Shape to suffer irreparable harm resulting from the loss of its lawful patent rights and the loss of its ability to exclude others from the market. On information and belief, Align will continue these infringing acts unless enjoined by this court.

**COUNT XXVII**  
**(Infringement of U.S. Patent No. 10,905,333)**

197. Counterclaim-Plaintiffs restate and reallege each of the foregoing paragraphs 1-196 of the Counterclaims as if fully set forth herein.

198. This cause of action arises under the patent laws of the United States, and in particular, 35 U.S.C. §§271, *et seq.*

199. The ’333 patent, entitled “3D intraoral scanner measuring fluorescence,” was duly and lawfully issued by the United States Patent and Trademark Office (“USPTO”) on February 2, 2021, to listed inventors Mike van der Poel and Karl-Josef Hollenbeck. 3Shape A/S is the owner by assignment of all right, title, and interest in and to the ’333 patent.



200. The ’333 patent discloses inventions related to a 3D scanner system configured for displaying a digital representation of a cariogenic region of a tooth and a digital 3D representation of a tooth. Such a 3D scanner has the advantage of allowing a user to not only view the surface of the tooth in three dimensions but also view the internal structure of the tooth to detect disease (e.g., cavities) without the need for a separate x-ray. The ’333 patent further advantageously describes that the 3D scanner can be configured to repeatedly change the operation of the scanner between the two configurations.

201. Align makes, uses, offers to sell, sells, imports, promotes and/or demonstrates versions of is iTero Element 5D, iTero Element 5D Plus, and iTero Element 5D Plus Lite scanners (collectively, the “iTero Element 5D Scanners”), including the wand, cart, and/or related software, and other related products in the United States.

202. 3Shape has good cause to believe that Align generally monitors 3Shape’s patents and patent prosecution at least because Align has filed IPRs on 3Shape patents before they were asserted in litigation or subject to any notice letter. Thus, on information and belief, Align possesses knowledge of, and is aware of, the ’333 patent.

203. Align has been and is now directly infringing, literally and/or under the doctrine of equivalents, at least claim 1 of the ’333 patent.

204. By way of illustration only, Align’s iTero Element 5D Scanners meet each element of claim 1 of the ’333 patent.

205. The iTero Element 5D Scanners are each “[a] 3D scanner system configured for displaying a digital representation of a cariogenic region of a tooth and a digital 3D representation of the tooth.” That system comprises “a 3D intraoral scanner device comprising: [1] one or more image sensor(s); [2] a first light source, the first light source configured to emit light at a first wavelength, wherein the 3D intraoral scanner device is configured such that at least one of the one or more image

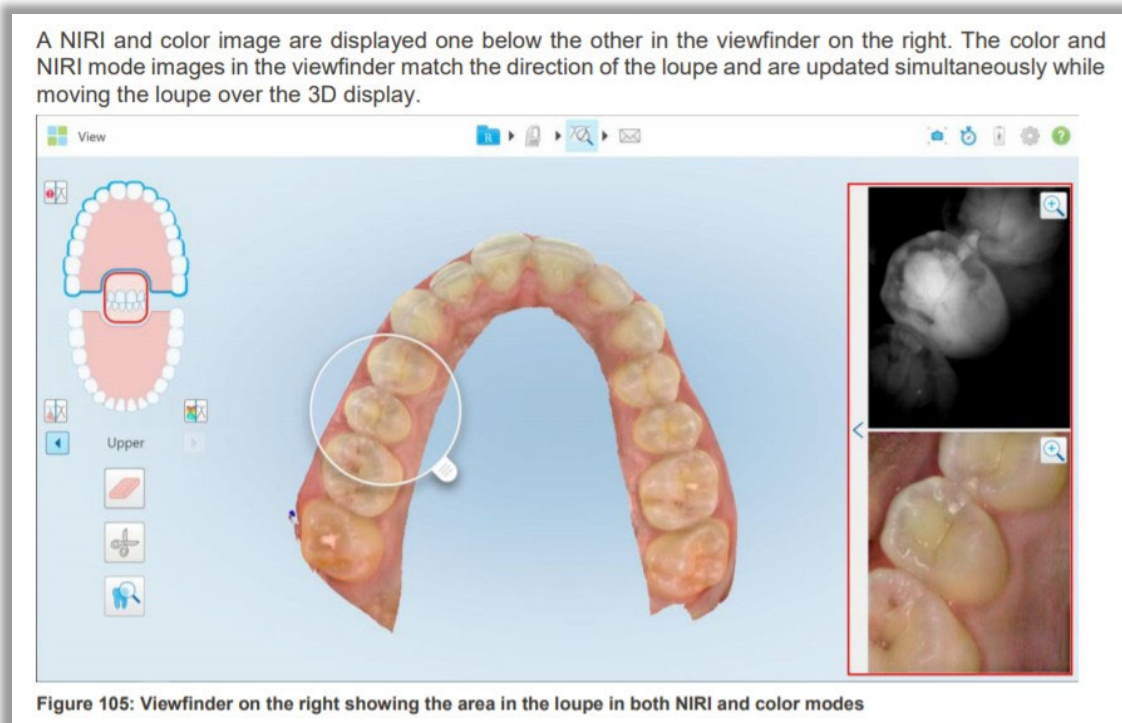
sensor(s) detects light at the first wavelength, thereby configured to record data for a 3D surface topography of the tooth; and [3] a second light source, the second light source configured to emit light at a second wavelength, wherein the 3D intraoral scanner device is configured such that at least one of the one or more image sensor(s) detects light at the second wavelength, thereby configured to record data for the cariogenic region of the tooth, a data processor configured for: [1] converting the data for the 3D surface topography of the tooth into the digital 3D representation of the tooth; and [2] converting the data for the cariogenic region into the digital representation of the cariogenic region of the tooth, a display configured for visualizing both the digital 3D representation of the tooth and the digital representation of the cariogenic region of the tooth, wherein the 3D intraoral scanner is configured to shift between the first light source and the second light source repeatedly, thereby configured to illuminate the tooth successively by the light from the first light source and the second light source.” (Ex. 4 at col. 32 ll. 6-41.)

206. Public documentation about Align’s scanners illustrate how the iTero Element 5D Scanners satisfy all elements of claim 1 of the ’333 patent. By way of example only, the website, user manual, brochure, and administrative filing below show that Align’s iTero Element 5D Scanners contain the infringing functionality. The iTero Element 5D Scanners are each a 3D scanner system configured for displaying a digital representation of a cariogenic region of a tooth and a digital 3D representation of a tooth. For example, the iTero Element 5D Scanners include a near-infrared imaging (NIRI) mode which is used to capture and display digital representations of cariogenic regions of a tooth along with the 3D representation of the tooth.



(iTero Element 5D (*available at* <https://iTero.com/oursolutions/iTeroelement5d>).)

207. In particular, the 3D representation of a patient's teeth is displayed in the center of the screen, while the NIRI mode image is displayed on a viewfinder to the right.



(iTero Element 5D User Manual at 84 (*available at* <https://storage-itero-production-us.s3.amazonaws.com/download/en-us/iTero-Element-5D-User-Manual.pdf>); *see also* Align iTero Element 5D 510(k) Summary (*available at* [https://www.accessdata.fda.gov/cdrh\\_docs/pdf19/K193659.pdf](https://www.accessdata.fda.gov/cdrh_docs/pdf19/K193659.pdf)) (The scanning wand which has 3 imaging capabilities: 1) 3D confocal optical impression, 2) 2D color imaging and 3) near infrared imaging (NIRI), is designed to be used with a single-use, disposable, scanning wand barrier sleeve (“5D barrier sleeve”) during scans and a protective sleeve during storage.... At the end of the scan, proprietary imaging software converts the scan into an image that is simultaneously presented alongside the 2D color images and NIR images on the GUI display.)

208. The iTero Element 5D Scanners are each a 3D intraoral scanner device.

The iTero Element 5D intra-oral scanner is Align Technology’s latest-generation integrated hardware (scanner) and software system.

This all-in-one system is available on a monitor with a fully interactive, touch-screen display and an easy-to-use wand. The topography of a patient’s teeth can be viewed on the screen as they are being scanned, and determining the degree of occlusion of the bite can be analyzed when the scan is completed.

The iTero Element 5D system combines:

- **3D scanning:** Recording and visualization of topographic 3D data and 2D imaging with an intra-oral camera.
- **NIRI technology:** Capturing data, to be used as a diagnostic aid for the detection of interproximal carious lesions above the gingiva and for monitoring the progress of such lesions. For more information on NIRI, see section 1.5.

(iTero Element 5D User Manual at 1.)

209. Further, the iTero Element 5D Scanners each include a color image sensor.

#### SCAN IN COLOR

Color scanning gives you a significant leap forward in visualization. The color sensor is integrated in iTero Element, and the patented dual-aperture lens system is designed to simultaneously capture 2D images in color with highly accurate 3D laser scanning. Color scanning can make it easier to immediately distinguish between gingival and tooth structures for a more precise clinical evaluation.

(iTero Element Brochure for General Practitioners at 4 (*available at*

<https://www.aligntech.com/documents/iTero-Element-Brochure-For-General-Practitioners.pdf>.)

210. The iTero Element 5D Scanners use a light source that emits a laser light at wavelength of 680nm to provide an optical 3D scan of the intra-oral cavity.

## Proven Imaging Precision.

The iTero® Intraoral Scanner is synonymous with high precision. Its parallel confocal imaging technology uses optical and laser scanning to achieve high precision and accuracy without powder or complicated hovering.

(*Id.* at 2.)



### SCAN IN COLOR

Color scanning gives you a significant leap forward in visualization. The color sensor is integrated in iTero Element, and the patented dual-aperture lens system is designed to simultaneously capture 2D images in color with highly accurate 3D laser scanning. Color scanning can make it easier to immediately distinguish between gingival and tooth structures for a more precise clinical evaluation.

(*Id.* at 4.)

#### System specifications – iTero Element 5D wheel stand configuration

<b>Monitor</b>	21.5" HD touch screen
<b>Wand</b>	The wand emits red laser light (680nm Class 1), as well as white LED emissions and 850nm LED emissions.

(iTero Element 5D User Manual at 133.)

211. In particular, 680nm laser light used to provide the optical 3D scan is captured using the color image sensor in the iTero Element 5D Scanners. (*See, e.g.*, Align iTero Element 5D 510(k) Summary at 6 (light detected by a “CMOS sensor”); iTero Element Brochure for General Practitioners at 3 (“iTero Element image sensor is designed to enable 20X faster scan speed versus the current iTero scanner.”), 4 (“The color sensor is integrated in iTero Element...”).

212. Further, the iTero Element 5D Scanners include two LEDs that emit red light with a wavelength of 850nm to image the internal structure and to detect cariogenic regions of a tooth.

### 1.5 Working with near infra-red imaging (NIRI)

NIRI is a method of spectroscopy that uses the near-infrared region of the electromagnetic spectrum (850nm).

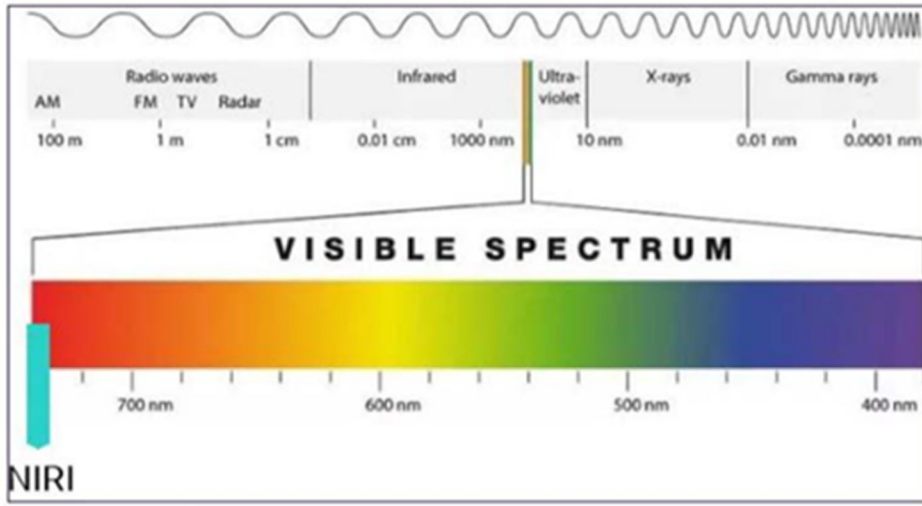


Figure 8: Visible light spectrum showing NIRI on the 850nm wavelength

When the wand is positioned above the tooth, NIR images will be captured.

(iTero Element 5D User Manual at 6); Align iTero Element 5D 510(k) Summary at 6 (“Two infrared light emitting diode (LED)s are used to generate exactly 850nm wavelength which are detected by the CMOS sensor.”)

The resulting NIRI grayscale image shows structures with varying translucency as different levels of brightness. The lower the translucency, the higher the reflection of the infrared light and the brighter the structure. Using this technology, it is possible to make out the following structures:

	Appears	Translucency
<b>Enamel</b>	Dark	High
<b>Interproximal caries</b>	Bright	Low
<b>Dentin</b>	Bright	Low

The differentiation between carious lesions and dentin is based upon the location of the bright feature. Dentin is located in the center of a tooth, whereas interproximal carious lesions appear on the interproximal or distal mesial region, where healthy enamel is expected.

As such, dentin and interproximal carious lesions appear as bright features, with a dark enamel ring around the dentin structure, as shown in the figure below, which provides an occlusal view of a carious lesion.

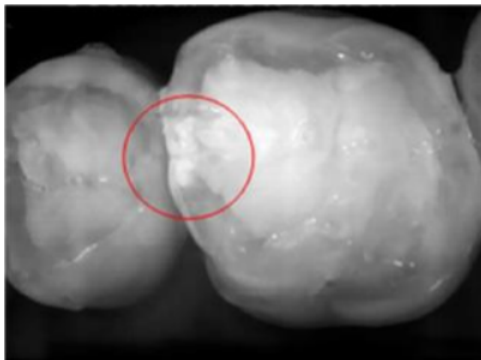
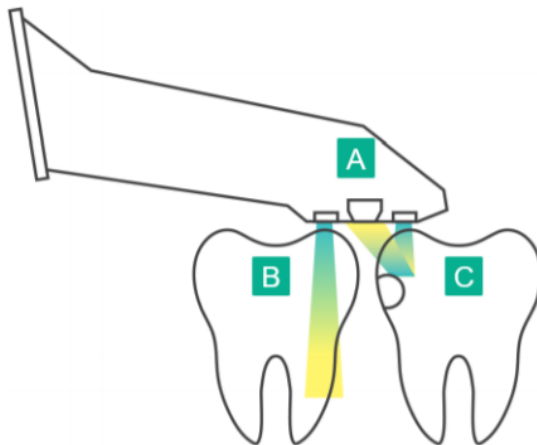


Figure 10: Interproximal carious lesion

(iTero Element 5D User Manual at 7.)

The translucency of the structure translates to the brightness level in the NIRI image – the higher the translucency, the darker the object, and vice versa. Tooth enamel is translucent to NIRI and will appear dark. Dentin and any interference in the enamel, e.g. caries, are reflective and cause the light to scatter, and therefore will appear brighter and opaque.



- A** Wand positioned on the tooth surface
- B** Tooth enamel is translucent
- C** Dentin and caries are reflective

Figure 9: Reflective concept – healthy enamel is translucent while dentin and caries are reflective

NIR images are captured automatically and seamlessly during the scan, from every angle used for the 3D scanning, and all collected information can then be reviewed using the iTero Element 5D Review tool.

(*Id.* at 6.)



213. Further, the 850nm LED light used to provide the NIRI imaging is captured using the color image sensor in the iTero Element 5D Scanners. (See, e.g., Align iTero Element 5D 510(k) Summary at 6 (light detected by a “CMOS sensor”); iTero Element Brochure for General Practitioners at 3 (“iTero Element image sensor is designed to enable 20X faster scan speed versus the current iTero scanner.”), 4 (“The color sensor is integrated in iTero Element...”)).

214. Further, the iTero Element 5D Scanners include a data processor to convert the data captured in 3D scanning mode into a 3D model of the tooth and to convert the data captured in the NIRI mode into an image of the cariogenic region of the tooth. In particular, software for the iTero Element 5D Scanners used to convert the data captured by the iTero Element 5D Scanners runs on an Intel processor.

The iTero Element 5D software can be installed on any laptop that meets the following requirements:		
Components		Requirements
Intel CPU	9th Gen Intel	Recommended: Intel® Core™ i5-9400H Intel® Core™ i5-9300H Intel® Core™ i7-9850H Intel® Core™ i7-9750HF Intel® Core™ i7-9750H Intel® Core™ i9-9980HK Intel® Core™ i9-9880H
Intel CPU	8th Gen Quad-core / Hexa-core Intel	Recommended: 6-Core i9: i9-8950HK 6-Core i7: i7-8850H / i7-8750H / i7-8700B Minimum: 4-Core i7: i7-8809G / i7-8709G / i7-8706G / i7-8705G
Intel CPU	7th Gen Quad-core Intel	Minimum: 4-Core i7: i7-7920HQ / i7-7820HQ / i7-7820HK / i7-7820EQ / i7-7700HQ

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(iTero Element 5D User Manual at 135; *see also* Align iTero Element 5D 510(k) Summary (“At the end of the scan, proprietary imaging software converts the scan into an image that is simultaneously presented alongside the 2D color images and NIR images on the GUI display.”))

215. Further, the iTero Element 5D Scanners include a display for visualizing both the digital 3D representation of the tooth and the digital representation of the cariogenic region of the tooth. (*See* iTero Element 5D User Manual at 84; iTero Element 5D Webpage.)

216. The iTero Element 5D Scanners are further configured to shift between the 680nm laser light source and 850nm red LED light source repeatedly to illuminate the tooth successively by the light from the first light source and the second light source.

NIR images are captured automatically and seamlessly during the scan, from every angle used for the 3D scanning, and all collected information can then be reviewed using the iTero Element 5D Review tool.

(iTero Element 5D User Manual at 6; *see also* Align iTero Element 5D 510(k) Summary.)

217. Align thus directly infringes, literally and/or under the doctrine of equivalents, at least claim 1 of the ’333 patent.

218. On information and belief, Align has directly infringed and continues to directly infringe the ’333 patent including by making, selling, offering for sale in the United States, and importing into the United States the iTero Element 5D Scanners.

219. Align also actively induces and has induced infringement of the ’333 patent under 35 U.S.C. §271(b). 3Shape has good cause to believe that Align generally monitors 3Shape’s patents and patent prosecution at least because Align has filed IPRs on 3Shape patents before they were asserted in litigation or subject to any notice letter. Thus, on information and belief, Align has knowledge of and is aware of the ’333 patent.

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220. Align encouraged and facilitated infringement with specific intent by, for example, training its customers to use the iTero Element 5D Scanners in a manner that infringes at least one claim of the ’333 patent, promoting the use of the iTero Element 5D Scanners in a manner that infringes at least one claim of the ’333 patent to Align’s customers, and disseminating promotional and marketing material and product literature to those customers encouraging use of the iTero Element 5D Scanners in a manner that infringes at least one claim of the ’333 patent.

221. Align’s customers for the iTero Element 5D Scanners directly infringe the ’333 patent by making, using, selling, offering for sale, and/or importing the iTero Element 5D Scanners.

222. Align has been and is now contributing to the infringement of the ’333 patent under 35 U.S.C. §271(c).

223. Align has actively, knowingly, and intentionally contributed and continues to actively, knowingly, and intentionally contribute to the infringement of the ’333 patent by selling or offering to sell, and continuing to sell or offer for sale the iTero Element 5D Scanners within the United States and/or by importing the iTero Element 5D Scanners into the United States with knowledge that the infringing technology in the iTero Element 5D Scanners is especially made and/or especially adapted for use in infringement of the ’333 patent, is a material part of the patented invention, and is not a staple article or commodity of commerce suitable for substantial non-infringing use and with knowledge that others including, but not limited to, resellers, distributors, customers, dentists, orthodontists, dental and orthodontic labs, and/or other end users of the iTero Element 5D Scanners do not have any substantial noninfringing uses. Align has such knowledge at least because the claimed features of the ’333 patent are used by others

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including, but not limited to resellers, distributors, customers, dentists, orthodontists, dental and orthodontic labs, and/or other end users of the iTero Element 5D Scanners.

224. Align has willfully infringed the ’333 patent. On information and belief, Align has known of the ’333 patent and has continued to infringe the patent in an egregious and wanton manner that Align knew or should have known amounted to infringement of the patent.

225. Align’s acts of infringement have injured and damaged 3Shape and will continue to injure and damage 3Shape.

226. Align’s actions have caused 3Shape to suffer irreparable harm resulting from the loss of its lawful patent rights and the loss of its ability to exclude others from the market. On information and belief, Align will continue these infringing acts unless enjoined by this court.

**COUNT XXVIII  
(Infringement of U.S. Re-exam Patent No. RE48,221)**

227. Counterclaim-Plaintiffs restate and reallege each of the foregoing paragraphs 1-226 of the Counterclaims as if fully set forth herein.

228. This cause of action arises under the patent laws of the United States, and in particular, 35 U.S.C. §§271, *et seq.*

229. The ’221 patent, entitled “System with 3D user interface integration,” was duly and lawfully reissued by the United States Patent and Trademark Office (“USPTO”) on September 22, 2020, to listed inventors Henrik Öjelund, David Fischer, and Karl-Josef Hollenbeck. 3Shape A/S is the owner by assignment of all right, title, and interest in and to the ’221 patent.

230. The ’211 patent discloses inventions related to a hand-held optical scanner for scanning a 3D environment that includes a motion sensor that can be used to remotely control the display connected to the hand-held optical scanner. In particular, the ’211 patent uses the motion

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detected by the motion sensor to control the display of the 3D environment represented on the display. The advantage of this remote control of the display is that it avoids the risk of cross-contamination due to interaction with other user interface devices (*e.g.*, mice, touch screens).

231. Align makes, uses, offers to sell, sells, imports, promotes and/or demonstrates versions of its iTero Element Scanners, including the wand, cart, and/or related software, and other related products in the United States.

232. 3Shape has good cause to believe that Align generally monitors 3Shape’s patents and patent prosecution, at least because Align has filed IPRs on 3Shape patents before they were asserted in litigation or subject to any notice letter. Thus, on information and belief, Align possesses knowledge of, and is aware of, the ’221 patent.

233. Align has been and is now directly infringing, literally and/or under the doctrine of equivalents, at least claim 33 of the ’221 patent.

234. By way of illustration only, the iTero Element Scanners meet each element of claim 33 of the ’221 patent.

235. The iTero Element Scanners are each “[a] scanning system for scanning a 3D environment.” That system comprises “[1] a handheld device including an optical scanner, wherein the 3D environment to be scanned is selected by pointing the optical scanner at the 3D environment; and [2] at least one display remotely connected to the handheld device, [3] wherein the handheld device is adapted for performing at least one scanning action in a physical 3D environment, and the at least one display is adapted for visually representing the physical 3D environment; and [4] wherein the handheld device includes at least one motion sensor for remotely controlling the display to adjust the view with which the 3D environment is represented

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on the display; and [5] wherein the at least one motion sensor is an accelerometer, gyro, or magnetometer.” (Ex. 7 at col. 17 l. 66 – col. 18 l. 17.)

236. Public documentation about Align’s scanners illustrate how the iTero Element Scanners satisfy all elements of representative claim 33 of the ’221 patent. By way of example only, the user manual, brochure, and training video below show that the iTero Element Scanners contain the infringing functionality. The iTero Element Scanners are handheld optical scanners used to scan intra-oral cavities by guiding the scanner in the intra-oral cavity.



(iTero Element Brochure for General Practitioners at 4 (*available at* <https://www.aligntech.com/documents/iTero-Element-Brochure-For-General-Practitioners.pdf>).)



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(*Id.*)

**SCAN IN MOTION**

Continuous scanning design lets you scan in motion—eliminating the need to click each time you want to capture a scan. The software automatically detects and repositions scanning start and stop points when you move to a new scanning position within the scanned segment.

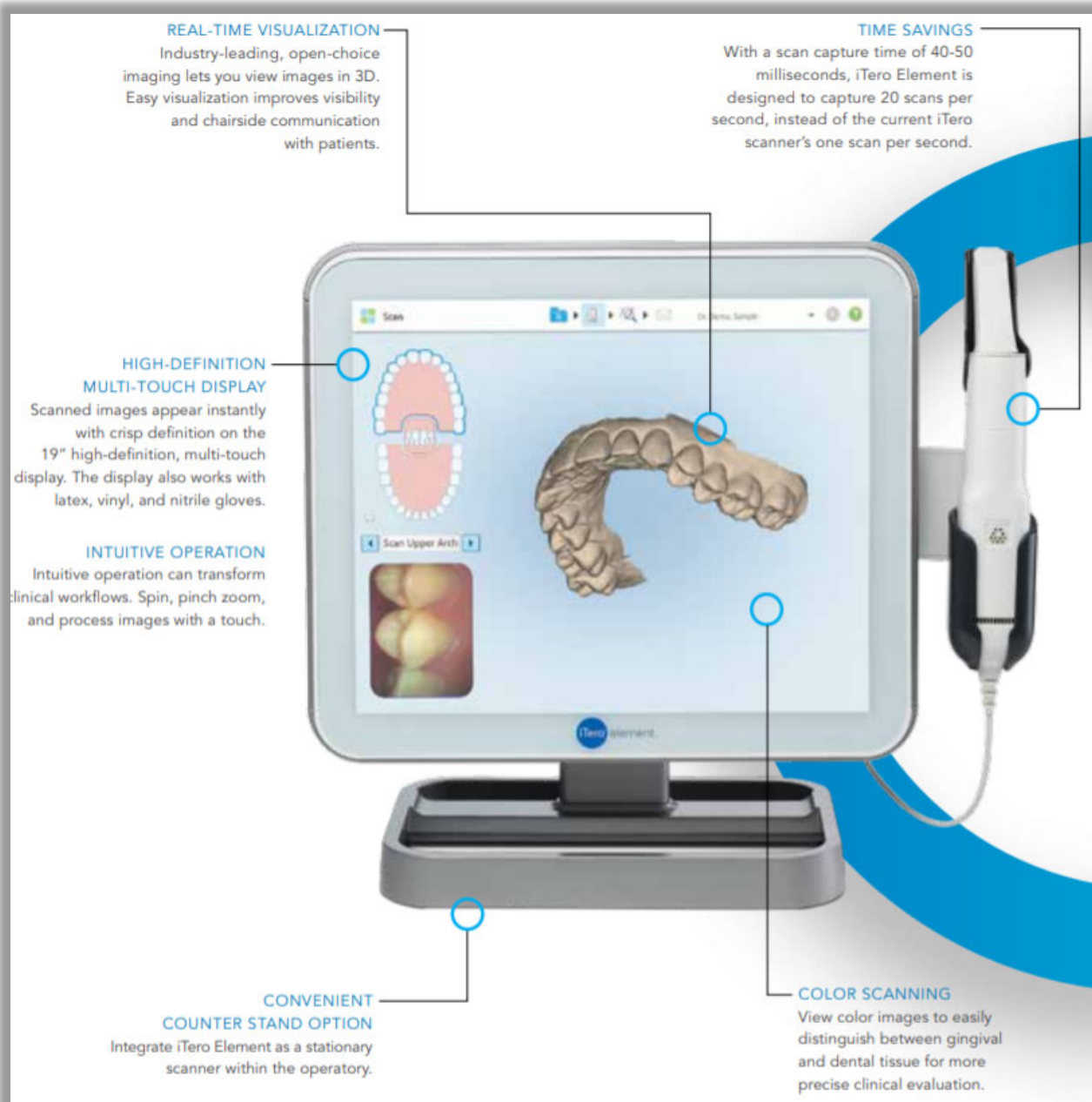
And while you are scanning, iTero Element is engineered to simultaneously process the scan. It automatically stitches together images for rendering in the correct order, adapts to changes in positioning, and detects and removes soft tissue. Capture everything. And view exactly what you need to see.

(*Id.*)

237. Further, the iTero Element Scanners include a display for visually representing the intra-oral cavity being scanned.



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(Id.)

238. The iTero Element Scanners further include a motion sensor (gyro) for remotely controlling the 3D model of the intra-oral cavity captured by the scanner.

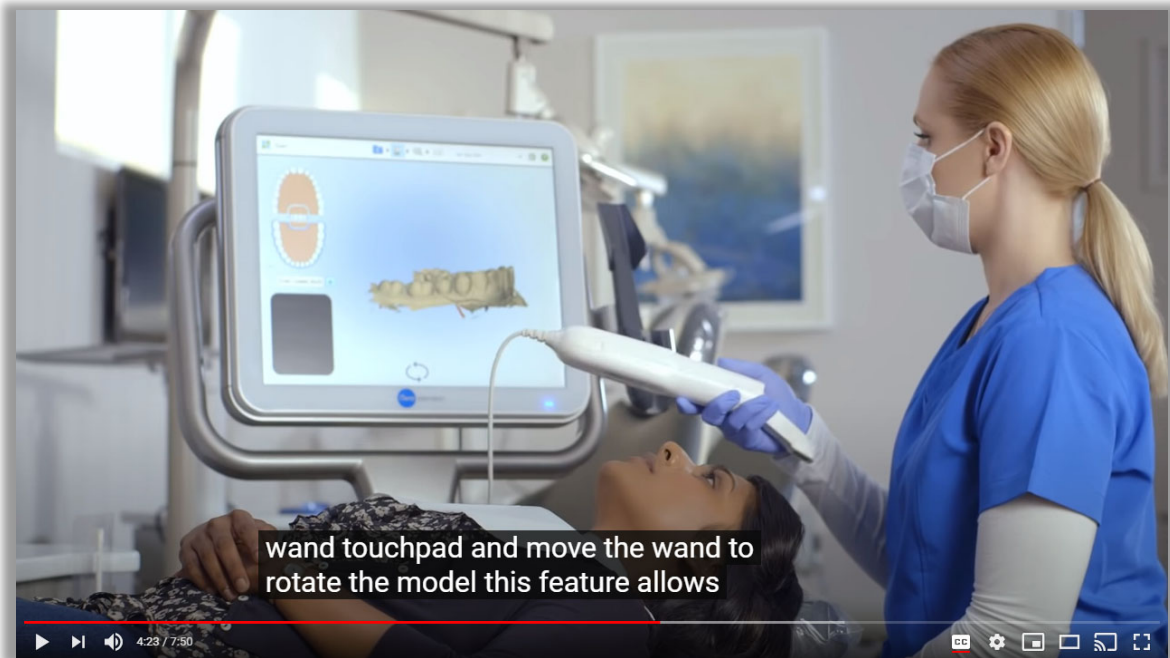


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### ADVANCED WAND FEATURES

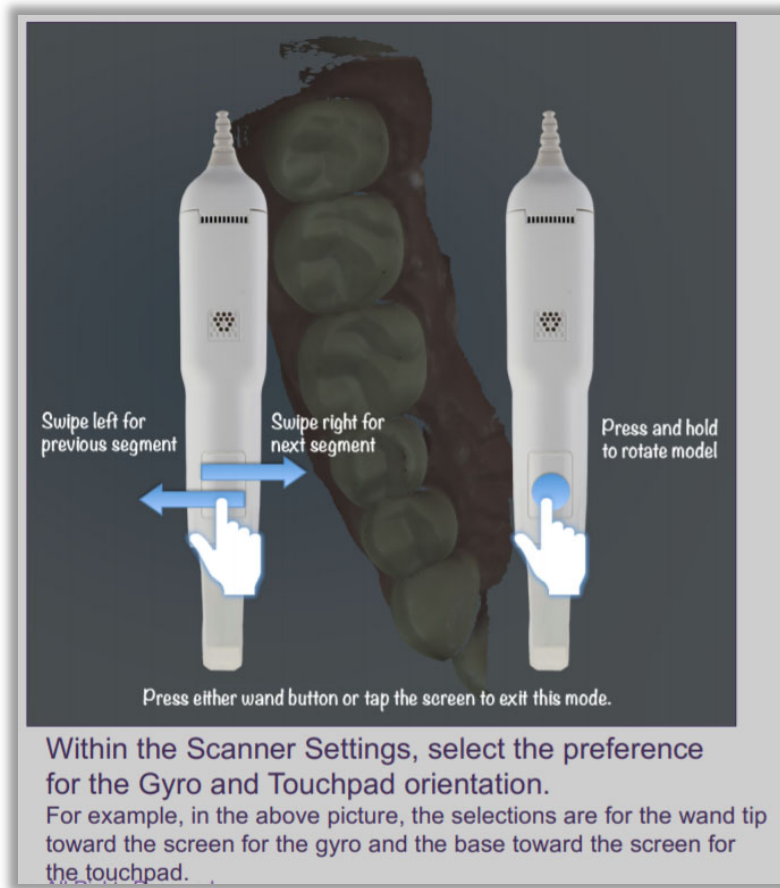
The redesigned wand features built-in controls, including side buttons and touchpad for user interface control. Integrated gyro technology lets you rotate models on screen. Plug and play wand cable quickly connects and disconnects to the base unit. And the patent pending ITO defogging system defogs instantly without needing air or extended warming.

(*Id.* at 3.)



(iTero Element® Orthodontic Training Video (*available at* <https://youtu.be/hDzBjbqD-KI?t=263>).)

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(iTero Element Intraoral Scanner Orthodontic Training Guidebook at 22 (May 2018) (*available at* <https://storagy-iTero-production-us.s3.amazonaws.com/download/en-us/iTero-Element-Ortho-Guidebook.pdf>).

239. Align thus directly infringes, literally and/or under the doctrine of equivalents, at least claim 33 of the '221 patent.

240. On information and belief, Align has directly infringed and continues to directly infringe the '221 patent including by making, selling, offering for sale in the United States, and importing into the United States the iTero Element Scanners.

241. Align also actively induces and has induced infringement of the '221 patent under 35 U.S.C. §271(b). 3Shape has good cause to believe that Align generally monitors 3Shape's patents and patent prosecution, at least because Align has filed IPRs on 3Shape patents before

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they were asserted in litigation or subject to any notice letter. Thus, on information and belief, Align has knowledge of and is aware of the ’221 patent.

242. Align encouraged and facilitated infringement with specific intent by, for example, training its customers to use the iTero Element Scanners in a manner that infringes at least one claim of the ’221 patent, promoting the use of the iTero Element Scanners in a way that infringes at least one claim of the ’221 patent to Align’s customers, and disseminating promotional and marketing material and product literature to those customers encouraging use of the iTero Element Scanners in a manner that infringes at least one claim of the ’221 patent

243. Align’s customers for the iTero Element Scanners directly infringe the ’221 patent by making, using, selling, offering for sale, and/or importing the iTero Element Scanners.

244. Align has been and is now contributing to the infringement of the ’221 patent under 35 U.S.C. §271(c).

245. Align has actively, knowingly, and intentionally contributed and continues to actively, knowingly, and intentionally contribute to the infringement of the ’221 patent by selling or offering to sell, and continuing to sell or offer for sale the iTero Element Scanners within the United States and/or by importing the iTero Element Scanners into the United States with knowledge that the infringing technology is especially made and/or especially adapted for use in infringement of the ’221 patent, is a material part of the patented invention, and is not a staple article or commodity of commerce suitable for substantial non-infringing use and with knowledge that others including, but not limited to, resellers, distributors, customers, dentists, orthodontists, dental and orthodontic labs, and/or other end users of the iTero Element Scanners do not have any substantial noninfringing uses. Align has such knowledge at least because the claimed features of the ’221 patent are used by others including, but not limited to resellers,

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distributors, customers, dentists, orthodontists, dental and orthodontic labs, and/or other end users of iTero Element Scanners.

246. Align has willfully infringed the ’221 patent. On information and belief, Align has known of the ’221 patent and has continued to infringe the patent in an egregious and wanton manner that Align knew or should have known amounted to infringement of the patent.

247. Align’s acts of infringement have injured and damaged 3Shape and will continue to injure and damage 3Shape.

248. Align’s actions have caused 3Shape to suffer irreparable harm resulting from the loss of its lawful patent rights and the loss of its ability to exclude others from the market. On information and belief, Align will continue these infringing acts unless enjoined by this court.

**PRAYER FOR RELIEF**

249. WHEREFORE, 3Shape respectfully requests that this Court enter a judgment in its favor and against Align as follows:

- A. Dismissing the Complaint with prejudice and entering judgment for 3Shape;
- B. Declaring that the claims of the ’433 patent are invalid and/or not infringed;
- C. Declaring that the claims of the ’519 patent are invalid and/or not infringed;
- D. Declaring that the claims of the ’151 patent are invalid and/or not infringed;
- E. Declaring that the claims of the ’152 patent are invalid and/or not infringed;
- F. Declaring that the claims of the ’527 patent are invalid and/or not infringed;
- G. Declaring that the claims of the ’609 patent are invalid and/or not infringed;
- H. Declaring that the claims of the ’936 patent are invalid and/or not infringed;
- I. Declaring that the claims of the ’519 patent are unenforceable for inequitable conduct and awarding 3Shape its reasonable attorneys’ fees.

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- J. Declaring that the claims of the ’151 patent are unenforceable for inequitable conduct and awarding 3Shape its reasonable attorneys’ fees.
- K. Declaring that the claims of the ’152 patent are unenforceable for inequitable conduct and awarding 3Shape its reasonable attorneys’ fees.
- L. Declaring that Align has infringed the ’815 patent directly, jointly, and/or indirectly by way of inducing and/or contributing to the infringement of the ’815 patent;
- M. Declaring that Align has infringed the ’711 patent directly, jointly, and/or indirectly by way of inducing and/or contributing to the infringement of the ’711 patent;
- N. Declaring that Align has infringed the ’333 patent directly, jointly, and/or indirectly by way of inducing and/or contributing to the infringement of the ’333 patent;
- O. Declaring that Align has infringed the ’221 patent directly, jointly, and/or indirectly by way of inducing and/or contributing to the infringement of the ’221 patent;
- P. Permanently enjoining Align and its officers, directors, agents, affiliates, employees, divisions, branches, subsidiaries, parents, and all others in active concert therewith from directly or indirectly infringing the Asserted Counterclaim Patents;
- Q. Ordering Align to pay 3Shape its damages, costs, expenses, and pre-judgment and post-judgment interest for Align’s infringement of the Asserted Counterclaim Patents, as provided under 35 U.S.C. § 284;

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- R. Ordering Align to pay treble damages as provided under 35 U.S.C. § 284;
- S. Finding that this is an exceptional case within the meaning of 35 U.S.C. § 285, and awarding 3Shape its reasonable attorneys’ fees;
- T. Finding business disparagement, unjust enrichment, tortious interference with prospective business relations, tortious interference with contractual relations, unfair competition, fraudulent inducement, and violation of the Lanham Act by Align.
- U. Awarding 3Shape the damages to which they are entitled by virtue of Align’s business disparagement, unjust enrichment, tortious interference with prospective business relations, tortious interference with contractual relations, unfair competition, fraudulent inducement, and violation of the Lanham Act;
- V. Permanently enjoining Align’s business disparagement, unjust enrichment, tortious interference with prospective business relations, tortious interference with contractual relations, unfair competition, and its violation of the Lanham Act;
- W. Awarding 3Shape the punitive damages to which they are entitled for Align’s conduct, including at least Align’s business disparagement, unjust enrichment, tortious interference with prospective business relations, tortious interference with contractual relations, unfair competition, fraudulent inducement, and violation of the Lanham Act.
- X. Awarding 3Shape their reasonable attorneys’ fees, costs, and expenses incurred in this action; and

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Y. Awarding any such other and further relief as this Court may deem proper,  
including, but not limited to, any enhanced damages for any of the  
aforementioned counterclaims.

Date: January 7, 2022

Respectfully submitted,

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***Counsel for Defendants and Counterclaim  
Plaintiffs 3Shape Trios A/S and 3Shape A/S***

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**CERTIFICATE OF SERVICE**

I certify that this document is been served on all counsel of record via the Court’s ECF system.

/s/ Max Ciccarelli

Max Ciccarelli